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## Gender Urology: Outcomes of urological care in gender affirming process

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2021

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### **citation for published version (APA)**

Pigot, G. L. S. P. (2021). *Gender Urology: Outcomes of urological care in gender affirming process: Gender Urology*. [PhD-Thesis - Research and graduation internal, Vrije Universiteit Amsterdam].

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## **GENDER UROLOGY**

**Outcomes of urological care in gender affirming process**

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## CHAPTER 1

### GENERAL INTRODUCTION AND OUTLINE OF THIS THESIS

Gender dysphoria (GD) is the deep feeling of discomfort that someone experiences when the gender at birth and gender identity do not match. Its classification is included in the fifth edition of the Handbook for the Classification of Mental Disorders (DSM-5®). In 2013 the DSM 5 has chosen to replace the term “gender identity disorder” by “gender dysphoria” (GD) in order to avoid stigmatization and to facilitate clinical care.[1] Transgender persons are individuals who have a gender identity or gender expression that differs from the sex assigned at birth, and they may desire gender affirming (GA) treatment to bring their physical sex in line with their gender identity. Gender neutral people (non-binary, non-confirming people) are people who identify as having no gender or being without gender identity.

Over the last decennia, the treatment of transgender and non-confirming people has become more accepted and accessible in many parts of the world. In 1979, this resulted in the foundation of the World Professional Association for Transgender Health (WPATH), an international multidisciplinary organization of health care professionals who by means of defining Standards of Care (SOC), has developed a manual to support quality of care of transgender and gender neutral people.[2] Multidisciplinary care includes psychology/psychiatry, endocrinology, gynecology, plastic surgery, urology and facial surgery. After successful completion of a psychological and hormonal phase transgender people may choose to advance to a surgical phase of the gender affirming process. In the VU University Medical Center individuals can proceed to the surgical phase of the genital Gender Affirming process when they meet the requirements of the SOC of the WPATH which are:

- Being GD diagnosed by a psychologist persistently and with documentation thereof
- Having the capacity to provide informed consent
- Being of an age reflecting majority (if younger follow the SOC for children and adolescents)
- If having any medical or mental health concerns, it should be well controlled
- Having two referrals from qualified mental health providers
- Having undergone 12 continuous months of hormone therapy in accordance with the individuals medical transition goal
- Having lived continuously for at least 12 months in the gender role that is congruent with their gender identity.

In recent years an increase in the number of people with GD is recorded and the number of transgender men (transgender man is a man who was assigned female at birth) nears that of transgender women (transgender woman is a woman who was assigned man at birth). This trend is seen worldwide, and it increases the pressure on existing centers for gender care as for waiting time and the number of care givers in this field.

For transgender men the surgical phase is the final chapter of their transition which can roughly be divided into three stages. During the first stage female sexual characteristics are adjusted, resected or removed (breast amputation also referred to as top surgery, salpingo-oophorectomy-hysterectomy and colpectomy). In the second stage masculine external genitalia are created; this is referred to as genital Gender Affirming Surgery (gGAS) or bottom surgery. The third stage consists of implantation of prostheses (penile and/or testicular implants). At the VU University Medical Center the urologist is involved in the second and third stage of the surgical phase.

The first reports on utilizing flaps to create parts of the male genitals date from the early 20<sup>th</sup> century. This concerned phalloplasty for cis gender male patients after traumatic penile injuries (cis gender people is a term denoting people in whom gender identity matches given identity) or agenesis of the penis.[3] These were the first publications giving insight into experience with the reconstruction of a phallus. These experiences were used in genital affirming operations in transgender men. This was first described by sir Harold Gillies in the 1940s.[4] Pedicled abdominal and later musculocutaneous (Orticochea 1972) flaps to create a urethra and a penile shaft were used in the early days until the introduction of the free radial forearm flap (FRFF) in the early 1980s by Song and Chang.[4,5,6,7] Utilization of a surgical microscope to create vascular anastomoses and neural anastomosis contributed to the successful use of these free flaps.[8,9] The FRFF enabled performing a tube in tube phalloplasty in a single stage and was considered the gold standard for phalloplasty at that time, due to reliability of the long vascular pedicle, pliability and flap thinness. Factors contributing to an aesthetically pleasing result. Donor site morbidity and the stigmatizing donor site scar of the forearm are disadvantages of this flap. Increased knowledge of the vascularization through perforators and innervation of novel donor sites has led to the development of new techniques.[10] Flaps like the anterolateral thigh (ALT) flap from the upper leg and the superficial circumflex iliac perforator (SCIP) flap from the groin lack the above named disadvantages and gain ground compared to the FRFF.

Another surgical technique to masculinize the genitalia of transgender men uses local tissue of the external genitalia (hypertrophied clitoris, labia minora and labia majora). Surgical transformation of female external genitalia to male external genitalia (penis and scrotum) in transgender men was first described by Durfee and Rowland in 1973 and was termed metoidioplasty by Laub.[11] Experience from hypospadias corrections gave a surgical base to further enhance this procedure. Current surgical options for gGAS in transgender men include pedicled or free phalloplasty, or metoidioplasty. At the VU University Medical Center gGAS in transgender men has been performed since the 1980's. Nowadays we have 12 different surgical techniques to be chosen from [12], all with their advantages and disadvantages. In a broad sense the advantage of a phalloplasty with urethral lengthening is a male like external genital with the possibility to void while standing out of the zipper. Furthermore, it enables insertion of penile implants to allow penetrative sexual intercourse. Disadvantages are donor site scars, and altered sensitivity of the external genitals. Advantages of metoidioplasty are inconspicuous scarring, and preservation of both tactile and erogenous sensitivity. Disadvantages are a small penile size, and the inability to have penetrative sexual intercourse. In the 1993 Hage and de Graaf published a list of criteria that a neo-phallus should fulfill. According to them the ideal neo-phallus is created in a single-stage, is aesthetically attractive, has tactile and erogenous sensation, confers minimal complications and donor site morbidity, and has a functional neo-urethra that permits voiding while standing. From a technical point of view the procedure should be easy to perform, and be reproducible.[13] Genital GAS was therefore defined as a phalloplasty or metoidioplasty with urethral lengthening (UL). Lengthening of the urethra, however, comes with high urological complication rates, e.g. urethral strictures and fistulae of 20-70 %.[14] These complications

result in high reoperation rates, causing physical and psychological distress.[15] Nowadays, during counselling for gGAS, the aim is to find the best treatment for each transgender man and thus striving for the ideal solution for each individual.[4,16,17]

If no complications occur after gGAS testicular prostheses are inserted after six months and penile prosthesis after one year presuming recovery of sensation in the flap. In case of complications, implants are placed at least 3 months after the last surgical procedure. Insertion of testicular prostheses after scrotoplasty is a simple procedure which can be performed in day care, and seems to have low complication rates. However, little evidence is available on this topic. In contrast, the implantation of a penile prosthesis in a phalloplasty poses major technical challenges, as corpora cavernosa to contain, and a tunica albuginea to keep a prosthesis in place, are missing. In the course of time, several materials have been used to achieve penile rigidity, ranging from biological materials such as rib cartilage and bone segments (e.g. fibula) to synthetic materials such as semi rigid and hydraulic cylinders.[18] To date, the use of biological materials is almost completely abandoned because of high complication rates or ineptness. However, also the synthetic penile prostheses show high complication rates, which are much higher compared to the application of this type of prostheses in cisgender men.[19]

The overview written above reflects the history of genital masculinizing surgery in transgender men in a broad sense. The initial era was marked by development of surgical strategies for the reconstruction of a male genital based on surgeon's capabilities, knowledge (different flaps) and experience, and the introduction of the surgical microscopes. This period was followed by an era characterized by a "pursuit of perfect genitalia" with the introduction of penile stiffening techniques (osteocutaneous flaps and penile implants) and neo scrotal augmentation implants (testicular implants), modifications depending on surgical expertise. Growth of experience has led to an increase of different techniques and procedures giving patients many choices. As a result, in the current era we notice a trend towards a more patient-centered care, where the surgeon's expertise and knowledge is combined with the expectations and desires of the individual, with the aim of achieving a tailored transition.[17] In this process of shared decision making, patients reported outcome measures (PROMs) are key elements. The PROMs aid both the care giver and the care taker. To date a universal PROM following gGAS in transgender men is not available. Although care for transgender people has been provided for a couple of decades, data on clinical outcomes and patients satisfaction is scarce. In the last decade an increase in scientific publications is noticed, instantiating the gender affirming care which traditionally consists of psychological assessment and counselling, hormonal therapy and surgery. Current data of PROMs have been derived from self-constructed questionnaires resulting in low level evidence and prohibiting dependable comparison between results from different studies.[20,21] Therefore, recently an international study protocol has been launched to develop a patient-reported outcome measure for adolescents and adults receiving gender-affirming treatments.[22]

## THE AIMS OF THE THESIS

This thesis focusses on those procedures in gGAS in transgender men in which the urologist is involved. The aim is to assess gGAS, and find ways of improving clinical outcomes as well as to increase patient satisfaction.

The aims of this thesis are threefold and it therefore is divided into three parts;

- Addressing urological complications in gGAS:
  - Assessing measures taken to prevent complication
- Outcomes of prosthetic surgery in transgender men after gGAS:
  - Assessing long term results and experience with testicular prostheses
  - Assessing long term results and experience with penile prostheses
  - initial results of a new malleable device specifically developed for phalloplasty's
- Shared decision making and patient reported outcomes after gGAS:
  - describing the development of a tool to assist the transgender man in their decision making process
  - assessing psychological and sexual functioning and well-being after gGAS in a small cohort of transgender men

The overall aim of the thesis is to increase knowledge, improve surgical techniques and outcomes of genital Gender Affirming Surgery in transgender men, and to gain insights in patient's expectations and experience after gGAS. Hence this thesis aims to take gender affirming care towards a higher level of evidence-based medicine.

## PART ONE

### Addressing urological complications in gGAS

GGAS in transgender men has traditionally been performed with UL, as voiding while standing has always been regarded as one of the goals to achieve. GGAS is known for having high (neo-urethral) complication rates. Performing a colectomy before gGAS with UL has been shown to be a major adjustment to prevent urethral complications after gGAS with UL [23].

Since construction of the neo-urethra is the most important risk factor, one would expect that gGAS without UL will reduce the number of post-operative urological complications. Chapter 2 analysis the surgical and functional outcomes and patient satisfaction following gGAS without UL and in Chapter 3 this surgical technique is displayed by video article.

One of the complicating factors following gGAS with UL is intra-urethral hair growth. Intra-urethral hair can be the cause of formation of hairballs and calculi leading to obstructive voiding necessitating operative or trans-urethral interventions.[24] A way to decrease complications after phalloplasty with UL is therefore preoperative depilation off the urethral donor site. Chapter 4 studies the effect of depilation on hair density of the neo-urethral donor site skin and the correlation between urethral hair density and voiding.

## PART TWO

### Outcomes of prosthetic surgery in transgender men after gGAS

A large number of transgender men wish to undergo prosthetic surgery after gGAS as well. In the literature data on testicular prosthetic surgery in transgender men is scarce, possibly because it is seen as minor and simple surgery performed in day care. Implants serve primarily to augment the neo-scrotum making it more masculine. Previously scrotoplasty consisted of double-sided inverted Y-V plasties of the labia majora with implantation of these prostheses at the same time. High post-operative complication rates (infections and erosion of the testicular implants) led to modification of the scrotoplasty technique and delayed insertion of testicular implants. Nowadays the neo-scrotum is reconstructed by mobilizing and medially rotating the labia majora in combination with a mobilized horse shoe shaped double pedicled pre-pubic flap. If no contra indications occur testicular prostheses can be implanted after 6 months. Chapter 5 describes the surgical outcomes of neo-scrotal augmentation with testicular prostheses in transgender men.

Implantation of a penile prosthesis, either hydraulic or malleable, may be requested as a final stage of gGAS. It typically causes rigidity of the phallus enabling penetrative intercourse. Although the majority of transgender men opting for phalloplasty also wish to have penile implants, some refrain from it as they are satisfied with sexual functioning without penetrative sexual intercourse, or because they are able to have penetrative intercourse without an implanted prosthesis, or they estimate the risk of complications too high. Although the functional results of hydraulic implants following gGAS are satisfactory as described in the literature, all studies report high complication and re-operation rates.[25] Chapter 6 reports the long term surgical results of penile implants inserted in the VU University Medical Center and Chapter 7 describes the multicenter outcomes of a new malleable penile implant.

## PART THREE

### Shared decision making and patient reported outcomes after gGAS

Traditionally, as seen through the eyes of the surgeon the “ideal neophallus” is defined as a reproducible “one size fits all” i.e. an aesthetically pleasing genital with sensibility, which allows for sexual intercourse and voiding while standing. However, by using this standard, or even by seeking one standard for the “ideal neophallus,” major advances having occurred in the (transgender) health care domain since 1993 have been ignored. Health care professionals should not be looking for one ideal neophallus, but for the ideal solution for each individual patient, demanding a broad surgical armamentarium with concern to gGAS. Individualizing this care is challenging for both patient and surgeon as multiple surgical options exist, each with their specific advantages, disadvantages, and risk of complications. The best choice depends on the individuals’ specific wishes, his physical condition and ability to cope with the burden of surgery, donor-site morbidity, and possible adverse events. Weighting all these issues to come to a tailor-made treatment requires shared decision making between the health care professionals and the care takers.[17] An instrument to balance the pros and cons of each type of surgery and in particular an accurate estimation of complication-risks is indispensable in the decision-making process. For this reason, a tool has been developed, together with transgender men, to support the decision-making process.

Chapter 8 describes the development of a decision-aid (DA) to assist transgender men in making their choice regarding GAS. Patient centered care has gained importance in the gender care. This emphasizes the need for data collection and assessment with regard to complications (short and long-term), aesthetic and functional outcomes and patient’s reported outcome. These data will enable to further develop transgender care.

Chapter 9 and Chapter 10 reports outcomes of post-operative psychological and sexual functioning and well-being following gGAS in transgender men. The instruments used are validated questionnaires developed for the cis gender population and non-validated self-constructed questionnaires specifically developed for the transgender population.

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**Part one**

**Addressing urological complications in gGAS**



## Chapter 2

### Genital Gender Affirming Surgery without urethral lengthening in transgender men. A clinical follow-up study on the surgical and urological outcomes and patient satisfaction

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#### ABSTRACT

##### Background

Genital gender affirming surgery (gGAS) with urethral lengthening (UL) in transgender men is associated with high urological complication and re-operation rates. Since 2009 we offer gGAS without urethral lengthening (UL) to avoid these complications.

##### Aim

The aim of this study was to assess what portion of the transgender men opted for gGAS without UL and to assess functional, surgical outcomes and patient satisfaction after gGAS without UL.

##### Material and methods

Retrospective data was collected from patients charts. The International Prostate Symptom Score (IPSS), uroflowmetry and 24 hour frequency voiding chart (FVC) were used to assess voiding and a self-constructed semi-structured questionnaire was used to assess patient reported outcomes. Transgender men who underwent gGAS without UL between January 2009 and January 2018 were included and 56 transgender men were approached to complete the PROM.

Simple statistical analysis combined with the Mann-Whitney U test and the Wilcoxon Signed Rank test were used.

##### Outcomes

68 transgender men were included. Median follow-up time was 24 (6-129) months.

Uroflowmetry and the IPSS were completed by 44 transgender men while 13 completed the FVC pre and post operatively respectively. The PROM was completed by 71% (40/56).

##### Result

Postoperative surgical and urological complications occurred in 13% (9/68) and 12%(8/68) patients, respectively. Storage and voiding function remained unchanged. The median quality of life (QoL) due to urinary symptoms was scored as "pleased". Sexual functioning and voiding were scored satisfactory and very satisfactory in respectively 45% (18/40) and 53% (21/40) of the patients. The number of patients satisfied with the penis and neo-scrotum were 63% (25/40) and 65% (26/40). Increased self-esteem was reported by 80% (32/40), 68% (32/40) would undergo the surgery again and 70% (28/40) would recommend it to others respectively.

##### Clinical Implications

GGAS without UL should be part of the surgical armamentarium in centers performing GAS.

##### Strength and limitations

Strengths of this study comprise the number of patients, the completeness of data, incorporation of patient-reported outcomes and description of a relatively new surgical approach that may be well-suitable for a subgroup of transgender men. Limitations are the retrospective study design and the lack of validated questionnaires.

##### Conclusion

GGAS without UL, shows good surgical and urological outcomes. After extensive counseling the majority of this selective group of patients show favorable patient reported outcomes.

## INTRODUCTION

Genital gender affirming surgery (gGAS) in transgender men in general consist of the reconstruction of a neo-scrotum and phallus with urethral lengthening (UL). In case of phalloplasty a penile stiffener may be inserted to enable sexual intercourse. Urological complications e.g. urethral strictures and urethral fistulae, are common after gGAS with UL (range between 50-70 %), are associated with psychological distress and have socioeconomic consequences (9,10). Treatment of these complications often require restorative surgical procedures, or sometimes long-lasting intermittent neo-urethral dilatation (9,10).

The requirements for masculinizing surgery are outlined by the Standards of Care (SOC) of the World Professional Association for Transgender Health (WPATH) (2). According to those standards, transgender men are considered eligible to proceed with the surgical phase of the transition when gender dysphoria is documented and diagnosed by a psychologist mental health professional, when having the capacity to provide fully informed consent, being of age of majority, having well-controlled medical or mental health concerns if present, having undergone 12 continuous months of hormone therapy in accordance with their medical transition goal and having lived continuously for at least 12 months in the gender role that is congruent with ones gender identity. Different gGAS techniques are described with the aim of creating a male genital in which the maintenance of urologic functions (micturition and sexual function) are important. In general, favorable results of satisfaction and sexual function are reported after gGAS (0,5,5).

In the Centre of Expertise on Gender Dysphoria at the Amsterdam UMC, VUMC (**Fout! Verwijzingsbron niet gevonden.**) a multidisciplinary team including the psychology, psychiatry, endocrinology, plastic surgery, urology and gynecology is involved in the (surgical) care. A surgical plan is made based on shared decision making and is supported by a decision aid (8), taking into account individuals preferences, the surgical possibilities (BMI, clitoral and labia minora hypertrophy, upper leg or flank thickness of subcutaneous tissue layer), outcomes of voiding assessment, realistic expectations and the psychological ability to cope with potential post-operative complications. The gynaecologist, plastic surgeon, urologist and psychologist are involved in the pre-operative counselling process for the gGAS.

In the VUMC, gGAS in transgender men was performed in two stages, with UL and the construction of a neo-scrotum first, followed by a secondary phalloplasty (6,7). Nowadays, gGAS in transgender men is a one stage procedure. The surgical options have traditionally been the metoidioplasty or the phalloplasty with UL. Since 2009, gGAS without UL has been offered at our center. We hypothesized that gGAS without UL would reduce post-operative urological complications and secondary procedures. In addition, we expected that extensive pre-operative counseling would increase post-operative satisfaction of surgical outcome and function. The aim of this study was to assess what portion of the transgender men chose gGAS without UL and to assess the urological and surgical outcomes and satisfaction after gGAS in this group of transgender men.

## **METHODS**

### **Patient selection**

In this follow-up clinical study, transgender men who underwent gGAS without UL between 2009 and 2018 with a post-operative follow-up time of at least 1 year were eligible to participate. Eligible participants were invited to complete a questionnaire assessing post-operative satisfaction.

### **Demographics and surgical and urological outcomes**

Age at gGAS, body mass index (BMI), follow up time, surgical characteristics: phalloplasty or metoidioplasty, phalloplasty flap type, intraoperative complications, postoperative complications (hematoma, skin necrosis and phalloplasty flap loss), urological complications (urethral fistula/stenosis and perineal orifice stenosis) were collected from the patients files.

### **Urinary function (storage and voiding) assessment**

All transgender men had storage and voiding function assessment which consisted of completion of the International Prostate Symptom Score (IPSS) questionnaire and a 24 hour frequency voiding chart (FVC) combined with performing a uroflowmetry. Scores of the IPSS between 1-7, 8-19 and 20-35 are indicative of respectively mild, moderate and severe symptoms. Scores of the quality of life (QoL) question range from 0 = delighted to 6 = terrible. There are no standards for a normal FVC, but a frequency around 6 times a day with voided volumes between 200 and 500 are regarded as normal storage function (11). With concern to the uroflowmetry, maximal voided velocity (Qmax) above 15 ml/s is indicative for absence of Bladder Outlet Obstruction (BOO) although consensus on the definition of BOO is lacking (12). Uroflowmetry with voided volumes above 150 ml were regarded as representative for the assessment of voiding. Patients with severe pre-operative pelvic floor dysfunction (established by IPSS, 24 hour FVC and the uroflowmetry) and accompanying dysfunctional voiding are advised to undergo gGAS without UL.

For the assessment of voiding the IPSS, functional bladder capacity and uroflowmetry were collected before and after the gGAS. Postoperative outpatient visits were scheduled after 3 weeks, 3 and 12 months, unless indicated otherwise.

### **Patient Reported Outcome Measurement (PROM)**

Data was collected using a non-validated self-compiled questionnaire with close-ended questions. A comprehensive concept questionnaire was compiled and the inputs of other medical specialties ( e.g. psychologist, plastic surgeon and psychiatrist) was obtained. In accordance with their input, changes were made to the questionnaire. This resulted in the PROM used in this study which comprised questions with concern to satisfaction of surgical outcome and function, feeling of masculinity and sexuality and was completed at least one year after the gGAS. Questions concerning satisfaction were ordinally scaled with 5 options ranging from 1 (the most favorable result) to 5 (the most unfavorable result). For the question concerning masculinity a ladder was used ranging from 0 not at all to 10 totally (see attachment). The questionnaire was digitally entered at a moment chosen by the patient in a private setting. In line with comments from the medical ethic committee a part of the study group was not approached to complete the PROM because they had already completed the more comprehensive questionnaire for another study.

### **Preoperative work up**

Transgender men were fully informed about all types of gGAS with and without UL. Expectations with concern to voiding, complications, aesthetic result and the possible need for additional surgical procedures were extensively discussed. All transgender men were consulted by a psychologist about their wishes and expectations of the surgery and an inventory is made about their psychological capacity and self-reliance in case of complications. Prerequisites for gGAS were having a BMI between 17 and 30 and refraining from smoking for at least 6 weeks. Flap choice is based on individuals preference, taking into account subcutaneous fat thickness. A maximum thickness of 1 cm of the donor site determined by ultrasound or pinch is mandatory to prevent too large phallic girth. For metoidioplasty, clitoral hypertrophy was a prerequisite for creating a micro-penis. The type of genital surgery is determined by the patients desire, psychological capabilities, surgical feasibility and the outcomes of the urological assessment. Pre-operative voiding assessment was performed as mentioned above. A colpectomy is mandatory in case of gGAS with UL as it has shown to reduce post-operative urethral strictures and fistulae (14). The colpectomy is performed during a separate surgical session and prior to the gGAS. In case of gGAS without UL, the colpectomy is optional and depends on the individuals desire.

The scrotoplasty is based on the scrotoplasty as developed by Hoebeke and Monstrey (13). The labia minora and a large part of its inner lining are resected leaving about one centimeter mucosa surrounding the urethral meatus. As a result, a wide urogenital opening at the perineal scrotal junction is created. The anatomical position of the urethral meatus remains unchanged. If the vaginal canal is preserved, the perineal orifice is referred to as the urogenital opening which allows voiding and drainage of vaginal discharge. In case the vaginal canal is removed, the orifice is referred to as a perineal urethrostomy which allows voiding. The clitoral skin is incorporated in the ventral part of the neo-scrotum. The perineum is lengthened by closing part of the perineal skin, making it more masculine. A 16 French trans urethral catheter is placed. The flaps used for the phalloplasty were the anterolateral thigh flap (ALT) from the upper leg or the superficial circumflex iliac perforator flap (SCIP) from the groin. Both are pedicled flaps with an easy to conceal and less conspicuous donor site. Because the flap sensory nerves must be spared, these flaps cannot be thinned out too rigorously. Appropriate thickness of these fasciocutaneous flaps is therefore important because this determines the final girth of the neo-phallus. The transurethral catheter is removed at day 4 or 5 (during hospital stay) so the transgender men leave the hospital without catheter. In comparison, our transgender men who undergo gGAS with UL have a hospital stay of approximately 7 days, and both a suprapubic and transurethral catheter for at least three weeks postoperatively. Postoperative outpatient visits are scheduled after 3 weeks, 3 and 12 months. Urinary storage and voiding assessment using the IPSS, 24 hour FVC and uroflowmetry is performed at 12 months postoperatively unless otherwise indicated.

Figure 1

## Data analyses

Continuous variables were presented as means with standard deviations or as medians with ranges. Descriptive analyses were performed using IBM SPSS Statistics Version 22 data analysis software (IBM Corp., Armonk, NY USA). The Mann-Whitney U test was used to compare the non-parametric continuous variables. The Wilcoxon Signed Rank test was used to compare the non-parametric paired continuous variables.

## Ethical statement

Approval was granted by the Medical Ethics Review Committee of VU University Medical Center under FWA number FWA00017598. Informed consent was obtained in all transgender men participating in this study before the start of surgical phase.

## RESULTS

Out of the 202 transgender men who had gGAS, 134 (66%) underwent gGAS with UL and 68 (34%) gGAS without UL and were included in the study. A metoidioplasty without UL and a phalloplasty without UL was performed in respectively 35 (52%) and 33 (48%) cases. An overview of the individuals characteristics is given in Table 1.

Of 68 transgender men, 66 consciously choose to undergo gGAS without UL. For this group, having no complications after surgery outweighed the urge to void while standing. Two (3%) transgender men who primarily preferred to have gGAS with UL where advised to refrain from this after pre-operative urological consultation with urinary function assessment. One was wheelchair bound because of a spinal cord injury and the second had severe pre-operative dysfunctional voiding due to pelvic floor dysfunction. Both indicated that they were satisfied with esthetical and functional result after the operation and both were content with the pre-operative counseling with concern to the decision to perform this procedure. There were no patients who indicated regret of gGAS without UL.

## Surgical complications

An overview of the surgical characteristics and complications is given in Table 2. No intraoperative complications occurred. Early postoperative surgical complications occurred in 9 out of 68 (13%) transgender men. Post-operative hematoma (three at the pubic area and one in the neo-scrotum) in 4 out of 68 (6%) which required surgical drainage. Necrosis of the phallus (all at the top of the phallus) occurred in 3 out of 68 transgender men (4%). All were treated with debridement and coverage with split skin graft. Complete phalloplasty flap loss (both ALT) was seen in 2 out of 68 (6%) transgender men for which a salvage phalloplasty (secondary phalloplasty) was performed at a later time.

**Table 2:** Surgical characteristics and complications

Surgical duration, minutes (range)	
Metoidioplasty	106 (60-199)
ALT	306 (210-433)
SCIP	200 (180-307)
Mean length of in-hospital stay, days $\pm$ SD	
Metoidioplasty	4.51 $\pm$ 1.12
ALT	6.5 $\pm$ 1.18
SCIP	6.18 $\pm$ 1.07
Intraoperative complications	0 (0%)
Postoperative complications*	9 (13,23%)
Hematoma	4 (5,8%)
Skin necrosis	3 (4,4%)
Phalloplasty flap loss	2 (5,7%)
Urethral fistula	0 (0%)
Urethral stenosis	0 (0%)
Perineostomy stenosis	8 (11,7%)

ALT=anterolateral thigh, SCIP= superficial circumflex iliac artery perforator, \*= within three weeks which required surgical correction

## Urinary complications and storage and voiding outcomes

Urinary complications occurred in 8 out of 68 (12%) transgender men and consisted of stenosis of the urogenital opening (n=5) and perineal urethrostomy stenosis (n=3). No urethral stricture or urethral fistula occurred. These stenosis were caused by contraction of the skin of the orifices and not by stenosis of the meatus of the urethra. A stenosis of the perineal urethrostomy caused obstructive voiding. In case of a stenosis of the urogenital opening, obstructive voiding, persistent fluid discharge and the feeling of voiding in the vaginal cavity were recorded. Transgender men who had not undergone a colectomy were treated by releasing the circular scar (episiotomy), mobilization of vaginal mucosa and suturing of the vaginal mucosa to the perineal skin in an interdigitated way to create a wider urogenital opening. In case a colectomy was performed, the circular scar was released and the meatus mobilized and spatulated. Hospital stay after this corrective surgery was two days and the transurethral catheter could be removed the day after surgery. No recurrence of urogenital opening or perineal urethrostomy stenosis occurred.

An overview of the storage and voiding function assessment pre-and postoperatively is presented in Table 3. The uroflowmetry was performed by 44 transgender before and after the gGAS. The IPSS was completed by 44 of them before and after the gGAS. The

transgender men were poorly motivated to complete the FVC post gGAS and in only 13 transgender men it was completed before and after the surgery. No changes were seen in pre- versus postoperative voiding and storage functions. This also accounts for the transgender men who underwent a colpectomy. No significant changes occurred in uroflowmetry (e.g., max flow rate, voided volume, time to max flow) pre- and post-operatively and no changes occurred in post residual volume. Furthermore, no significant changes occurred in IPSS score. There was however, a statistically significant decline of the QoL score of the IPSS ( $p=0.037$ ) going from 0 (delighted) to 1 (pleased) ( $n=44$ ). With concern to the FVC there was no difference in day frequency, night frequency and functional bladder capacity when comparing the group of patients who completed the FVC before and after the gGAS ( $n=11$ ).

**Table 3:** Urinary voiding assessment pre-and postoperatively. The data is from the transgender men who completed the assessment.

	Pre-operative	n	Post-operative	n	P-value
Uroflowmetry <sup>mwu</sup>					
Max flow rate, ml/s (range)	26 (6,2-84)	44	28.3 (10-80)	44	0.526
Average flow rate, ml/s (range)	14 (2-49)	35	13 (2-49)	26	0.671
Flow time, s (range)	22 (6.9-54.3)	35	19 (4.9-125)	26	0.699
Time to flow max, s (range)	5.7 (0.8-25.1)	35	6.3 (1.5-20)	26	0.274
Voided volume, ml (range)	263 (19.7-896)	44	311 (27-792)	44	0.381
Post residual volume, ml (range)	0 (0-90)	44	0 (0-250)	44	0.249
IPSS score (range) <sup>mwu</sup>	4 (0-22)	37	5 (0-23)	30	0.216
Quality of life (range)	0 (0-4)	37	1 (0-6)	30	0.037*
Frequency voiding chart <sup>w</sup>					
Day frequency	7.4 (3-14)	13	7.5 (4-17)	13	P=0.952
Night frequency	1 (0-1)	13	2 (1-3)	13	P=0.952
Functional bladder capacity	390 (200-610)	13	405 (250-830)	13	P=0.552

<sup>mwu</sup>=The Mann-Whitney U test is used to compare pre-and postoperative outcomes,

<sup>w</sup>= The Wilcoxon Signed Rank test is used to compare the paired data pre-and postoperative,

\*=significant at significance level of 0.05

### Patient reported outcome measurement

From the 68 transgender men 12 were not approached as they already completed the more comprehensive PROM. The excluded group had gGAS during the same timeframe and had the same pre-operative counseling and post-operative follow up. From the 56 eligible transgender men, 16 could not be reached and 40 completed the PROM (response rate 71%). Figure 5 shows the flow chart of included transgender men and table 4 displays the results of the PROM. The small majority of transgender men were satisfied or very satisfied with the esthetical results of the penis (63%) and neo-scrotum (65%). Around 50% were satisfied or very satisfied with the functional outcome (e.g. voiding and sexual functioning). The vast majority agreed or strongly agreed that the surgery increased their self-esteem (80%), would recommend the surgery to others (70%), would undergo the surgery again (77%) and indicated that the outcomes match their expectations (78%). We found no associations between complications and results from the PROM. Responses of the satisfaction with sexual function question are summarized in table 5.

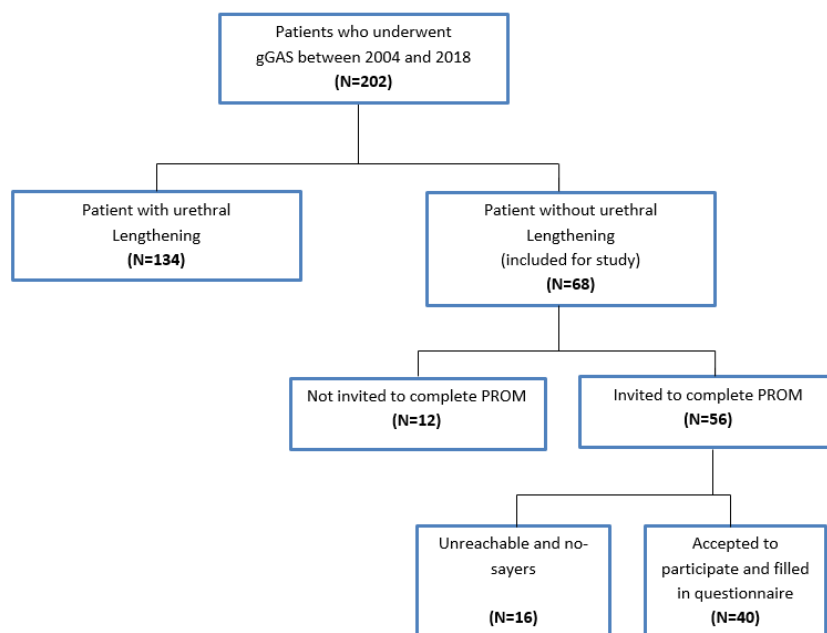


Figure 5 Flow chart of transgender men eligible for completion of the PROM

**Table 4:** Results from the patient reported outcome measurement

	Very satisfied (1)	Satisfied (2)	Neutral (3)	Unsatisfied (4)	Very unsatisfied (5)
How Satisfied are you with:					
The appearance of your penis?, n (%)	9(22.5)	16(40)	7(17.5)	6(15)	2(5)
The appearance of your scrotum?, n (%)	5(12.5)	21(52.5)	8(20)	4(10)	2(5)
Your current voiding pattern?, n (%)	7(17.5)	14(35)	14(35)	4(10)	1(2.5)
Your sex life?, n (%)	2(5)	16(40)	13(32.5)	6(15)	3(7.5)
The sexual functioning of your penis?, n (%)	2(5)	16(40)	13(32.5)	6(15)	3(7.5)
	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree(5)
To what extent do you agree with the following statements:					
The surgery increased my self-esteem as a man. n (%)	15(37.5)	17(42.5)	7(17.5)	1(2.5)	0
I would recommend this surgery to others.n (%)	18(45)	10(25)	9(22.5)	0	3 (7.5)
Looking back, I would undergo the surgery all over again. n (%)	26(62.5)	6(15)	7(17.5)	1(2.5)	1(2.5)
The surgical outcomes match my expectations. n (%)	8(20)	23(57.5)	4(10)	4(10%)	1(2.5%)

**Table 5** Summary of responses of the satisfaction with sexual function question  
metoidioplasty

satisfaction	n	Responses
Very satisfied	0	Feeling of the phallus is good.
Satisfaction	10	The phallus feels like a real penis The sexual feeling is unchanged I have orgasms
Nor satisfied or unsatisfied	7	No partner, not sexually active, low sexual desire, feeling is good but small for penetration
Unsatisfied	3	Unable to penetrate
Vey unsatisfied	1	Not much has changed Too small to penetrate

satisfaction	n	Responses
Very satisfied	2	Feeling of the phallus is good.
Satisfaction	6	Although I cannot penetrate my orgasm is good and the feeling in the phallus is getting better. More confidence because of sexual intercourse
Nor satisfied or unsatisfied	6	Sometimes penetration is painful for partner. Asexual relation
Unsatisfied	3	No penile implant jet,
Vey unsatisfied	2	Malposition of the penile implant No feeling in the phallus Phallus is to short

## DISCUSSION

This clinical follow up study of gGAS without UL shows favorable surgical and urinary function outcomes (storage and voiding function). A urinary complication rate around 10 % was recorded (e.g. stenosis of the perineal orifice), which is significantly lower than urinary complications after gGAS with UL reported in the literature (10,10). Still, a small majority of transgender men were satisfied and very satisfied with the functional outcomes. The main reason for dissatisfaction with sexual function was the absence of a penile implant (which they were still awaiting for). With concern to voiding, around 50% were satisfied and very satisfied, while 35% scored neutral. Objective urological outcomes, however, showed good functional results. The vast majority of transgender men agreed and strongly agreed the surgery increased their self-esteem, would recommend it to others, would undergo the surgery again and indicated that the outcomes matched their expectations. These results show predominant favorable outcome after gGAS without UL as seen from a care takers point of view. Additional benefits of gGAS without UL is a less visible donor site in of the ALT flap and the SCIP flap compared to the free radial fore arm flap.

Since we offer transgender men a choice to undergo gGAS with or without UL, one third deliberately chose to refrain from UL and as stated before, for this group, having no complications after surgery outweighed the urge to void while standing. For two transgender men the circumstances were decisive in the decision to undergo gGAS without UL.

Personal preference of the transgender men was also decisive with concern to the colpectomy. Performing a colpectomy has a number of advantages; it can have an effect on the male self-esteem (e.g. no vaginal discharge during arousal, and by closing the vaginal cavity a more masculine perineum is created) (15). It also proved to reduce urethral fistulas in case of gGAS with UL (14). At our centre the colpectomy is mandatory before gGAS with UL. The colpectomy, however, is a challenging procedure that comes with potential complications of the lower urinary tract system, intra-operative blood loss and postoperative voiding complaints (15). In case of gGAS without UL a colpectomy can be omitted and therefore the concomitant complications can be avoided.

In this study, we were able to demonstrate the anticipated benefits of this procedure with concern to the peri- and postoperative outcomes. No urethral fistulas or strictures occurred postoperatively. Both complications predominantly occur at the transition of the fixed to the pendulant part of the neo-urethra after gGAS with UL and are not expected as this part is only created when performing gGAS with UL. In this cohort eight transgender men developed obstructive voiding due to stenosis of the skin that surrounds the urethral meatus. In those, a minor surgical revision was performed. Patients were discharged from the hospital one day postoperatively without a transurethral catheter. The removal of the transurethral catheter one day post-operatively is justified by the fact that we did revise the urethral meatus, but only the surrounding skin. The reduction of complications compared to transgender men who undergo gGAS with UL is associated with less secondary operations and outpatient hospital visits, which may have a positive effect on total healthcare costs in this population.

With concern to urinary storage and voiding function , there was no difference in IPSS scores, FVC and uroflowmetry pre-and postoperatively. The QoL with concern to voiding increased with one point, from delighted to pleased which was a statistical significant decline. This statistical significant increase showed no clinical consequence as there was no difference in IPSS score before and after the gGAS without urethral lengthening. As the anatomical position of the urethral is unchanged one would expect no change in voiding. For this the placing a supra pubic catheter becomes due (which is the standard during gGAS with UL in most centers) and the transurethral catheter is removed during the hospital stay and when patient are mobilizing. In our experience the catheter is removed on day 4 or 5 and thus patient

leave the hospital without catheter. One transgender man in this selective group indicated that he is not able to fully live as a man because he is unable to void standing. Another one was unable to use a special voiding devise after the gGAS which enabled him to void while standing before the operation. Other reasons for dissatisfaction with voiding were: voiding against the scrotum, problems with urinating and discomfort at the perineal orifice. For the majority in this selective group, voiding while sitting is not seen as a shortcoming and one can postulate that this does not negatively influence the gender dysphoria. We have to be cautious with this however as the questions on the effect of voiding in a sitting position on gender dysphoria in transgender men was not addressed.

Results after GAS show high satisfactory results with concern to esthetical and functional outcomes, while rates of dissatisfaction and regret are low. Causes of dissatisfaction and regret can be related to unmet expectations, treatment outcomes or complications and can occur throughout the transition process(5). In this study no transgender man indicated regret after genital GAS without UL. Dissatisfaction (unsatisfied or very unsatisfied) with esthetical and functional surgical outcomes were scored however by a minority of transgender men in this study but did not result in regret. Extensive pre-operative counseling during this shared decision making process contributed to these results. The outcomes of the open questions (table 5) will aid in further developing of the pre-operative counseling process. It should be noted that UL in a later stage would be challenging since the labia minora and infundibular tissue (needed for pars fixa creation) are excised.

GGAS has proven to positively influence sexual functioning with concern to masturbation, use of genitals during sex, engaging in sexual relations and sexual role (3,4,5). At the time of completion of the PROM about 50 % of transgender men were satisfied or very satisfactory with the sexual function. For the transgender men with phalloplasty's this is partly due to the lack of a penile implant which they were still awaiting for and lack of sensitivity in the phallus. For the transgender men with a metoidioplasty the lack of length and the inability to have sexual intercourse was the main reason for dissatisfaction. In accordance to previous studies gGAS increased self-esteem and the outcomes after surgery matched the expectations (3,4,5). The results (with concern to sexual functioning and wellbeing) from these studies and the results of the PROM used in our study, emphasize the importance of extensive and thorough pre-operative counseling of these transgender men, where personal preferences, expectations and goals are weighted out against outcomes and limitations in order to make a tailored decision based on shared decision making. Results of pre-operative counseling and PROMs were already emphasized in previous studies(3). At our center a decision aid is developed through collaboration with health care professionals and representatives of the transgender association. This decision aid helps transgender men to make a well-considered decision with regard to GAS (8).

Strengths of this study comprise the number of patients, the completeness of data, and the incorporation of patient-reported outcomes. This has resulted in the thorough description of a surgical approach that may be suitable for a subgroup of transgender men. This is the first publication on gGAS without UL and therefore we have chosen to focus on describing the technique and showing outcomes after the procedure and partly comparing it with outcomes before the procedure. In later studies we will compare gGAS without to gGAS with UL. Limitations of this study included: the relatively low number of transgender men who completed the urinary function assessment and the exclusion of transgender men who completed the more comprehensive questionnaire. Another limitation is that the IPSS was used, for it is not validated for transgender people. Still, we think that it is of value as it contains questions which address both the storage and voiding phase and the outcomes indicate symptoms in both female and male patients. Furthermore, this is the only validated questionnaire available for assessment of voiding function in patients without incontinence for urine. A non-validated PROM which was developed by the health professionals was used. It is difficult to state what the influence of the gGAS without UL was on the assessed parameters from the PROM and whether there is a relationship between the surgery and the outcomes. Still we think the outcomes give an indication about the results of the gender affirming process on a whole. As the operative phase was part of the affirming process in this study, outcomes of this PROM also reflect on outcome of the surgical phase in this highly selected and well counseled group. Moreover, some of the questions specifically addressed the influence of the gGAS. The fact that the majority of this group would recommend the surgery to others also says something about the whole affirming process in this selected and well counseled group of transgender men. So with the interpretation of these results one has to keep in mind that this is a selected group who were extensively counseled and were motivated to undergo this procedure.

## Conclusion

In our population of transgender-men opting for gGAS, one third chose to undergo this without UL after extensive pre-operative counseling. The procedure shows low complication rates with preservation of storage and voiding function. Favorable results with concern to patients satisfaction is reported after surgery emphasizing the importance of thorough patient counseling and shared decision making. GGAS without UL is a valuable option which should be included in the pre-operative counseling and should be incorporated in the surgical armamentarium of surgeons in centers specialized in masculinizing genital gender affirming surgery.

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## Chapter 3

### Scrotal reconstruction in transgender men undergoing genital gender affirming surgery without urethral lengthening: a stepwise approach.

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#### Abstract

**Background:** Scrotal (re)construction, scrotoplasty, is performed as part of gender affirming surgery in transgender men.

**Objective:** To describe, step-by-step, our scrotal reconstruction technique in transgender men undergoing genital gender affirming surgery without urethral lengthening.

**Material and methods:**

A twenty-nine-year-old transgender man underwent scrotal reconstruction and phalloplasty without urethral lengthening. For this purpose, the traditional scrotal reconstruction technique in patients that undergo urethral lengthening had to be modified. The patient is placed in lithotomy position. A pedicled horseshoe-shaped pubic flap, clitoral hood and U-shaped labia majora flaps are used for scrotal reconstruction. The inner part of the labia minora (this is used to reconstruct the fixed part of the neourethra) is resected. The cranially pedicled U-shaped labia majora flaps are rotated 90 degrees medially to bring the neo-scrotum in front of the legs. Pedicled labia majora fat pads (LMFP) are released bilaterally and relocated in the neo-scrotum to achieve bulkiness. The meatus and vaginal orifice are diverted underneath the scrotum and a perineostomy is performed.

**Results:** We present our scrotoplasty technique as a step-by-step video guide. The technique results in the reconstruction of a perineostomy at the perineal scrotal transition, an augmented neo-scrotum, minimal visible scars and proper neo-perineal length.

**Conclusion:** Scrotal reconstruction using a horseshoe-shaped pedicled pubic flap, LMFP and two cranially pedicled U-shaped labia majora flaps results in a neo-scrotum that resembles the biological scrotum closely in terms of bulkiness, size, shape, tactile sensation and anatomical position.

## Chapter 4

### Effectiveness of Preoperative Depilation of the Urethral Donor Site for Phalloplasty: Neourethral Hair Growth and its Effects on Voiding

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#### ABSTRACT

##### Background:

For transgender men choosing to undergo phalloplasty with urethral lengthening, there is a potential for hair growth in the neourethra. Depilation of the urethral donor site may reduce subsequent intraurethral hair-growth.

**Objectives:** To evaluate the effectiveness of preoperative laser depilation and assess the correlation between urethral hair density and voiding among transgender men undergoing phalloplasty with urethral lengthening.

**Design, setting, and participants:** This was a retrospective study of 25 transgender men undergoing phalloplasty with urethral lengthening between July 2010 and April 2015 at the VU University Medical Center in Amsterdam.

**Intervention:** Phalloplasty with urethral lengthening using skin with or without pre-operative depilation.

**Outcome measurements and statistical analysis:** Data on preoperative laser depilation treatments were obtained from the local laser center. Intraurethral images were captured via urethroscopy and used to rate hair density. Images of the contralateral forearm were used as a reference. Hair density was rated in terms of the number of hairs per view as zero, low (1–9), moderate (10–19), or high (>20). Voiding was assessed using the International Prostate Symptom Score (IPSS) questionnaire, a 24-h voiding diary, and uroflowmetry.

**Results and limitations:** Twenty-five patients underwent urethroscopy. In the depilation group (n = 14) the hair reduction was significant and hair density was downgraded on average by 1.0 points (95% confidence interval [CI] 0.5–1.5). The mean number of laser treatment sessions was 6 (range 2–10). In the no-depilation group (n = 11), hair density did not significantly differ between the urethra and the contralateral arm (mean difference 0.18, 95% CI 0.5–0.9). The majority of the patients reported mild voiding complaints (median IPSS score 7, range 2–28) and had a normal functional bladder capacity and a non-obstructed urinary flow with low postvoid volumes.

#### INTRODUCTION

A significant number of transgender men opting for genital gender affirming surgery prefer phalloplasty with urethral lengthening [1]. This requires lengthening of the urethra with at least 13 cm of additional neourethra. Several techniques have been described for urethral lengthening. The free radial forearm flap (FRFF) is the most widely used flap to create a neourethra in a neophallus [2]. One of the disadvantages of the FRFF is the potential for hair growth in the neourethra as the forearm skin is hair-bearing.

Urethral reconstruction surgery using hair-bearing scrotal skin in repair of hypospadias and urethral strictures is associated with urinary tract infections, trichobezoars (hair-balls), urethral calculi, and dysuria [3–5]. To reduce problems associated with intraurethral hair, transgender men who present at our institution with moderate to significant hair growth at the urethral donor site are advised to undergo laser depilation treatment of the donor site before surgery. The success of laser treatment depends on skin type, hair color and thickness, the laser settings, and the number of laser sessions [6]. The appropriate treatment, including the number of sessions necessary and laser settings, are determined by the laser center.

Little is known about the effectiveness of preoperative laser depilation of the donor site to prevent intraurethral hair growth or about voiding function in relation to hair growth in the neourethra. The aims of this study were as follows:

- 1 To compare hair density (HD) between the neourethra and the contralateral forearm in transgender men who underwent phalloplasty with urethral lengthening;
- 2 To assess the effectiveness of hair removal using laser or intense pulsed light (IPL) at the urethral donor site before phalloplasty; and
- 3 To determine the association between urethral HD and voiding complaints.

## PATIENTS AND METHODS

### Patients

In this retrospective study, transgender men who underwent phalloplasty with urethral lengthening between July 2010 and April 2015 at the VU University Medical Center (VUMC) in Amsterdam were identified and invited to participate. Phalloplasty was performed using either an FRFF or a pedicled anterolateral thigh flap (ALT) in combination with an FRFF. The neourethra was constructed in a tube-in-tube fashion with an FRFF and as a separate FRFF in combination with an ALT. The indication for depilation of the neourethra donor site was determined by one of the plastic surgeons via subjective judgment of the amount of hair on the forearm. Among all patients undergoing phalloplasty with urethral lengthening during the study period, hair depilation was indicated in 42%. All patients were informed about the study by their attending doctor and via letter. The patients were divided into depilation and no-depilation groups. The protocol was approved by the Medical Ethics Review Committee of VUMC. All patients provided written informed consent.

### Depilation

The method and characteristics of hair removal treatment for each individual were determined by the individual depilation centers. Laser, IPL, and electro optical synergy hair removal techniques were used in these specialized centers.

### Outcome measures

Standardized urological postoperative follow-up for transgender men involves assessment of voiding. This includes UF and completion of a 24-h voiding chart and the International Prostate Symptom Score (IPSS) questionnaire.

Urethroscopy was performed at least 6 months after phalloplasty to assess HD in the neourethra. A flexible cystoscope was used to take intraluminal pictures of the part of the neourethra with the highest HD and subsequently from the corresponding place of the contralateral forearm. HD in images was rated independently by a urologist, a plastic surgeon, and a dermatologist who were blinded to the depilation groups. HD was assigned a score on a four-point scale: 0 = no hair; 1 = mild (1–9 hairs per view); 2 = moderate (10–19 hairs per view); and 3 = severe (>20 hairs per view; Fig. 1). HD on the contralateral forearm was used as a reference in evaluating the effect of depilation. Voiding was assessed using the IPSS and UF. Maximum flow velocity ( $Q_{max}$ ) of 10 ml/s was considered indicative of bladder outlet obstruction. The association between  $Q_{max}$  and HD was assessed by dichotomizing these two parameters ( $Q_{max} > 10$  vs 10 ml/s; HD 0–1 vs 2–3).

### Statistical analyses

Statistical analyses were carried out using SPSS v.22.0 (IBM Corp., Armonk, NY, USA) and statistical significance was set to  $p < 0.05$ . Descriptive statistics are used to present outcome measures. The Kolmogorov-Smirnov test was used to test for normality of the distribution of each numeric variable. The mean and standard deviation (SD) are presented for normally distributed variables and the median and range for non-normally distributed variables. Means were compared using a two-sided Student's *t* test and medians using the nonparametric Fisher exact for ordinal variables.

## Classification

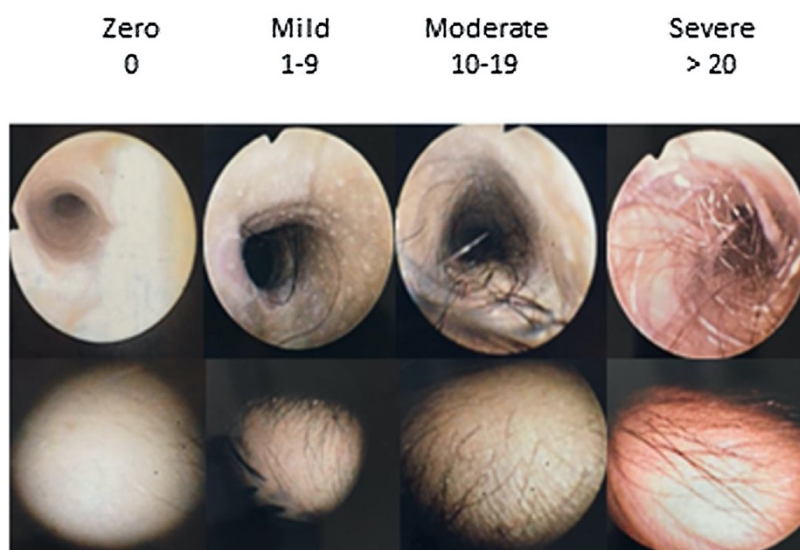


Fig. 1 – Classification of hair density (HD) in terms of hairs per view. The upper row shows pictures taken via a flexible cystoscope from the part of neourethra with the greatest hair density. The lower row shows pictures taken using a flexible cystoscope of the greatest hair density on the contralateral forearm.

## RESULTS

### Patient characteristics

Twenty-five patients were included in the study. An FRFF was used in 14 cases and a combined ALT with FRFF in 11 cases. The mean age of patients at the time of surgery was 33.8 yr (SD 8.4). The mean time between surgery and urethroscopy was 23.6 mo (SD 14.6). The median follow-up was 23 mo (range 4–55) in the depilation group and 24 mo (range 2–48) in the no-depilation group. Table 1 provides an overview of the patient characteristics and perioperative results. Table 2 shows detailed information for hair measurements and urological assessment for individual patients.

**Table 1** – Patient characteristics and perioperative details.

	No depilation	Depilation
Patients (n)	11	14
Procedures (n)		
Free radial forearm flap	8	6
Anterolateral thigh flap + free radial forearm flap	3	8
Mean age (yr)	33	34
Mean body mass index (kg/m <sup>2</sup> )	25.7	24.3
Mean operating time (min)	378	435
Intraoperative complications (n)	0	0
Mean hospital stay (d)	8.6	8.7
Mean postoperative transurethral catheterization (d)	16	24
Mean preoperative Q <sub>max</sub> (ml/s)	22	23
Mean postoperative Q <sub>max</sub> (ml/s)	15	17
Short-term complications (%)	54	50
Long-term complications (5)	80	71
Q <sub>max</sub> = maximum flow velocity.		

### Laser treatment

Preoperative depilation of the donor site was indicated in 14 (FRFF = 6, ALT + FRFF = 8) of the 25 patients (Table 1). Our data show that the indication for laser treatment, according to a retrospectively developed grading system, was moderate to high HD. Data on the number of epilation sessions were available for all but two patients (Table 2). The mean number of sessions was six (range 2–10).

Table 2. Overview of individual patient characteristics and laser and urological results.

Patients	LTX	HU	HA	dHU-HA	IPSS	QoL	VV	PRV	Q <sub>max</sub>	Voiding	frequency		FBC
	(n)						ml	ml	(ml/s)		day	night	ml
depilation													
1	9	H	H	0	18	3	X	X	X	X	11	1	225
2	X	H	H	0	6	2	80	0	26	NOV	8	0	592
3	3	H	M	1	X	X	393	152	15	NOV	X	X	X
4	8	M	H	-1	X	X	300	100	18	NOV	X	X	X
5	4	M	M	0	17	4	338	0	15	NOV	8	0	440
6	5	L	M	-1	0	0	65	0	18	NOV	4	0.5	325
7	6	L	M	-1	19	4	320	0	20	NOV	9	1	400
8	10	L	H	-2	5	2	181	92	7	OV	6	0	200
9	10	L	H	-2	28	5	107	20	12	NOV	12	0	400
10	4	L	H	-2	7	2	202	97	6	NOV	8	0	200
11	6	L	M	-1	7	4	440	0	24	NOV	5	1	300
12	5	L	M	-1	8	1	300	17	22,3	NOV	6	1	450
13	X	L	H	-2	26	5	410	0	20	NOV	10	0	350
14	2	L	H	-2	4	0	125	0	23	NOV	8	0	200
No depilation													
1	-	H	H	0	26	6	112	50	2,4	OV	5	2	250
2	-	H	M	1	7	1	240	0	12	NOV	13	2	300
3	-	L	L	0	7	2	240	113	4,2	OV	7	0	485
4	-	L	M	-1	5	5	242	35	12	NOV	5	0	350

5	-	L	L	0	9	2	210	40	23	NOV	8	1	370
6	-	L	M	-1	13	3	375	26	16,4	NOV	13	2	270
7	-	L	L	0	X	X	161	0	5,1	OV	X	X	X
8	-	L	M	-1	1	0	365	235	43	NOV	6	0	370
9	-	0	0	0	12	4	382	8	11	NOV	8	0	440
10	-	0	L	-1	2	0	332	0	9,1	OV	5	1	340
11	-	M	H	-1	4	1	540	51	3,08	NOV	7	0	700

LTx = laser treatment; HD = hair density (H = high, M = medium, L = low); HU = HD in the urethra; HA = HD for the contralateral arm; DHU-HA = difference in HD; IPSS = International Prostate Symptom Score; QoL = quality of life score; VV = voided volume; PRV = postvoid residual volume; Qmax = maximum flow velocity; X = not known; OV = obstructed voiding (Qmax 10 ml/s); NOV = nonobstructed voiding; FBC = functional bladder capacity.

#### HD measurements

HD on the forearm at the time of urethroscopy was significantly higher in the depilation than in the no-depilation group (Table 3). Hair in the neourethra did not differ between the groups. The median difference in HD score between the arm and neourethra was significantly greater in the depilation group (median 0.5 vs 1.0;  $p = 0.04$ ). Depilation resulted in a significantly lower HD in the neourethra compared to the "control" arm (Table 3). No bezoars or calculi were observed in the neourethra during urethroscopy.

**Table 3.** Hair density measurements

Group	Median hair density score (range) <sup>a</sup>		
	Contralateral arm	Neourethra	$\Delta$ HD
No depilation	2 (0-3)*	1 (0-3)	0.5 (-1-1)**
Depilation	3 (2-3)*	1 (1-3)	1 (-1-2)** <sup>Y</sup>

$\Delta$ HD = difference in hair density between the neourethra and contralateral arm.

<sup>a</sup> Hair density scores: 0 = no hairs; 1 = mild; 2 = moderate; 3 = severe.

\* Hair density differs significantly between the groups (independent-sample Fisher's exact test:  $p = 0.043$ , test statistic = 4.79,  $n = 22$ ).

\*\* DHD differs significantly between the groups (independent-sample Fisher's exact test:  $p = 0.040$ , test statistic = 5.39,  $n = 22$ ).

<sup>Y</sup> DHD is significantly greater than 0 (one-sample Wilcoxon signed rank test:  $p = 0.015$ , test statistic = 42.5,  $n = 12$ ).

#### Voiding and IPSS results

Voiding results are summarized in Table 4. There was no association between IPSS and HD. A Q<sub>max</sub> indicative of bladder outlet obstruction (10ml/s) was found in six patients, two in the depilation group and four in the no-depilation group. In these cases a urethral stricture was identified as the cause of the obstruction and there was no association with HD. None of the other voiding parameters (day and night frequency, residual urine, functional bladder capacity) were associated with neourethral HD.

**Table 4** – Voiding outcomes by neourethral hair density

Measure	Overall cohort	n	Neourethral hair density			
			Low	n	High	n
International Prostate Symptom Score	7 (0-28)	22	7.0 (0-28)	16	7 (4-26)	6
Quality of life score	2(0-6)	22	2 (0-5)	16	2(1-6)	6
Voided volume (ml)	300 (65-540)	24	296 (65-440)	17	319 (80-540)	7
Maximum flow velocity (ml/s)	15.(2.4-43)	24	14.2 (4.2-43)	17	12(2.4-30-8)	7
Postvoid residual volume (ml)	20 (0-235)	24	18.5 (0-235)	16	25 (0-100)	6
Daytime frequency (n)	8 (5-13)	22	8 (5-13)	16	8.0 (5-13)	6
Nighttime frequency (n)	1 (0-2)	22	1 (0-2)	16	0 (0-2)	6
Functional bladder capacity (ml)	350 (200-700)	22	337.5 ± 93.6	16	361.4 ± 153.4	6

<sup>a</sup> Data are presented as median (range) or mean ± standard deviation. There were no significant differences between the low (0–1) and high (2–3) hair density groups.

## DISCUSSION

Hair growth in the urethra is a known phenomenon in urethral reconstructive surgery and several publications have addressed the clinical consequences of and treatment possibilities for this problem [3–5]. When urethroplasty is performed using scrotal or penile skin flaps, abundant hair follicles are the source of urethral hair.

Studies suggest that it is not the hair itself but the secondary formation of urethral calculi and bezoars that is the cause of voiding complaints [4]. These manifest in irritation of the urethra, painful and obstructed voiding, and recurrent urinary tract infections. Whether hair in the absence of secondary calculi and bezoars can cause voiding complaints has not been addressed in the literature. Studies have shown that a significant obstruction in the urethra is unlikely for urinary flow velocities exceeding 10–15 ml/s [7].  $Q_{max}$  of 10 ml/s was measured in only one out of seven transgender men with moderate to high neourethral HD, and this patient appeared to have a urethral stricture. By contrast,  $Q_{max}$  of 10 ml/s was measured in five transgender men with a HD score of 0–1, all caused by a urethral stricture. The same was true for HD and lower urinary tract symptoms (LUTS) measured using the IPSS: there was no association between urethral HD and IPSS. In this study with a small cohort and relatively short follow-up, voiding complaints were correlated with urethral stricture disease and not with neourethral HD. Other possible causes of obstructed voiding can be lack of compliance of the pendulant part of the neourethra and the length and diameter of the neourethra.

However, our data also show moderate to high HD scores for men in the no-depilation group. This may be indicative of a lack of consensus regarding preoperative assessment of HD. A study by Wierckx et al [8] showed that an important increase in body hair growth and distribution can be expected even after 1 yr of testosterone treatment [8]. Theoretically, this phenomenon could also explain the high HD scores in the no-depilation group. To obtain a more objective rating, a grading system for HD was developed (Fig. 1) to compare intraurethral HD with the contralateral forearm. Data for the no-depilation group show that hair growth on the forearm is a good reflection of urethral hair growth.

We found a lower rate of hair growth in the depilation than in the no-depilation group. Hair depilation was performed in various specialized centers and the treatments were highly variable. For this reason and owing to the limited number of patients, it is not possible to identify the optimal treatment settings. According to our current protocol, transgender men are seen at least 6 wk after the last laser session for a definitive assessment of HD of the donor site. In the context of the variable length of the follicle cycle, it is questionable whether 6 wk is a long enough interval to declare a forearm as sufficiently hairless. This might not be the case, as in our series there were no hair-free neourethras.

Is postoperative laser treatment of a “hairy” neourethra an option in the case of complications? Previous studies accepted a maximum of 80% hair reduction by depilation as a good result [9,10]. However, this is for skin that is easily accessible (axilla, legs, face) for repeat laser treatment. Laser depilation of the urethra is a technical challenge and there are no laser devices specially designed for intra-urethral hair depilation to date.

In our opinion, creating a complete hairless neourethra from preoperative depilated skin is not possible. There are literature reports on cisgender patients with urethral hair after the use of hair-bearing scrotal skin for urethral reconstructions who were treated with an intraurethral Nd-YAG laser [9,11] or installation of thiogluconate acid [10,11]. Calculi or bezoars of the urethra can be treated by rinsing out the urethra, although larger stones or bezoars may require open surgery [12]. In our study, none of the patients had urethral calculi or bezoars. This is probably because of the relatively short follow-up.



This study is limited by the small number of patients, the short follow-up, the retrospective analysis, and the subjectivity in scoring HD. Owing to the retrospective design, we were not able to use a control group. However, we assessed hair growth on the contralateral arm to assess the change in HD. We could show that hair growth on the forearm is a good reflection of urethral hair growth in the no-depilation group.

Our study with median follow-up of almost 2 yr did not reveal any association between urethral HD and urinary flow rate or voiding complaints. However, on the basis of evidence from the literature, we would still recommend preoperative depilation of the skin at neourethral donor sites to decrease the chances of the formation of hairballs and calculi in the neourethra over time.

## CONCLUSIONS

Preoperative laser depilation reduces hair growth in the neourethra compared to the forearm in the majority of transgender men. However, laser depilation did not result in a hairless neourethra. In the short term, neourethral hair does not appear to influence urinary flow velocity or LUTS.

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## **Part two**

### **Outcomes of prosthetic surgery in transgender men after gGAS**

## Chapter 5

### Surgical Outcomes of Neoscrotal Augmentation with Testicular Prostheses in Transgender Men

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#### ABSTRACT

**Introduction:** Testicular prosthesis implantation may be used for neoscrotal augmentation in transgender men.

**Aim:** Assess the clinical outcomes and risk factors for postoperative complications of this procedure in trans- gender men.

**Methods:** All transgender men who underwent neoscrotal augmentation with testicular implants between January 1992 and December 2018 were retrospectively identified. A retrospective chart study was performed that recorded surgical characteristics and postoperative complications. Risk factors on complications were identified using uni- and multivariate analyses.

**Main Outcome Measure:** Surgical outcomes included explantation due to infection, extrusion, discomfort, or leakage.

**Results:** We identified 206 patients, and the following prostheses were placed: Dow Corning (n 1/4 22), Eurosilicone (n 1/4 2), Nagor (n 1/4 205), Polytech (n 1/4 10), Promedon (n 1/4 105), Prometel (n 1/4 22), Sebbin (n 1/4 44), and unknown (n 1/4 2). The mean clinical follow-up time was 11.5 ± 8.3 years. In 43 patients (20.8%), one or both prostheses were explanted due to infection, extrusion, discomfort, prosthesis leakage, or urethral problems. Currently, scrotoplasty according to Hoebeke is the most frequently performed technique. Our review found that for this technique explantation occurred in 6 of 52 patients (11.5%). A history of smoking was a risk factor for postoperative infections and prosthesis explantation. In earlier years, larger prostheses were immediately placed at scrotal reconstruction; however, a trend can be seen toward smaller and lighter testicular prostheses and delayed implantation.

**Clinical Implications:** Patients wanting to undergo this procedure can be adequately informed on postoperative outcomes.

**Strengths & Limitations:** Strengths of this study include the number of patients, long clinical follow-up time, and completeness of data. Weaknesses of this study include its retrospective nature and the high variability of prostheses and surgical techniques used.

**Conclusion:** Over the years, scrotoplasty techniques and testicular prostheses preferences have changed. Explantation rates have dropped over the last decade.

#### INTRODUCTION

The number of transgender people who seek gender affirmation treatment has increased internationally in the last decade.<sup>1,2</sup> Some transgender men opt to undergo genital gender affirmation surgery (GAS), which may consist of either metoidioplasty or phalloplasty. For metoidioplasty, after the clitoris hypertrophies from testosterone treatment, the clitoral corporal body is then freed by releasing the urethral plate and suspensory ligaments and is covered by local skin of prepuce and labia minora. An urethra can be formed out of labial tissue with or without buccal mucosa inlay grafts. In phalloplasty, free or pedicled adipocutaneous flaps are used to construct the phallus. Generally, postoperative satisfaction is high.<sup>3-5</sup>

Surgical construction of the neoscrotum (scrotoplasty) can be performed in multiple way.<sup>6</sup> For example, a scrotum may be created by performing a bilateral dorsal V-Y advancement of the labia majora with subsequent testicular prosthesis implantation, such as described by Hage.<sup>7</sup> Disadvantages of this approach include the position of the scrotum (between the legs), because the perineum is not lengthened, and the bifid appearance caudally, which may be perceived as unnatural. Many different V-Y-based labial approaches are described for midline fusion. Hoebeke described a scrotoplasty using V-Y advancement of the major labia together with rotation of the cranially based labial.<sup>8</sup>

Augmentation of the neoscrotum can be achieved with transposition of prepubic fat during the primary genital gender affirmation surgery; however, testicular implants better resemble biological testicles with regard to shape and size. Long-term clinical outcomes of neoscrotal augmentation with testicular prostheses are lacking in current literature. The objective of this study was to assess the clinical outcomes and risk factors for postoperative complications of this procedure in transgender men. The study protocol was approved by the institutional medical ethical committee.

#### METHODS

##### Retrospective Chart Study

All transgender men who underwent neoscrotal augmentation with testicular implants between January 1992 and December 2018 were retrospectively identified from the hospital registry. A retrospective chart study was performed that recorded patient demographics (age at implantation, body mass index, use of medication, history of smoking, history of drug abuse, and American Society of Anesthesiologists

physical status classification); surgical characteristics (type of scrotal reconstruction, prosthesis specifications, direct or delayed implantation, other procedures performed at prosthesis implantation); and post-operative complications (explantation, extrusion, infection, relocation, or leakage). Clinical follow-up, defined as the time between surgery and the last visit at either the plastic surgery or urology outpatient clinic, was noted.

### Scrotal Reconstruction Techniques

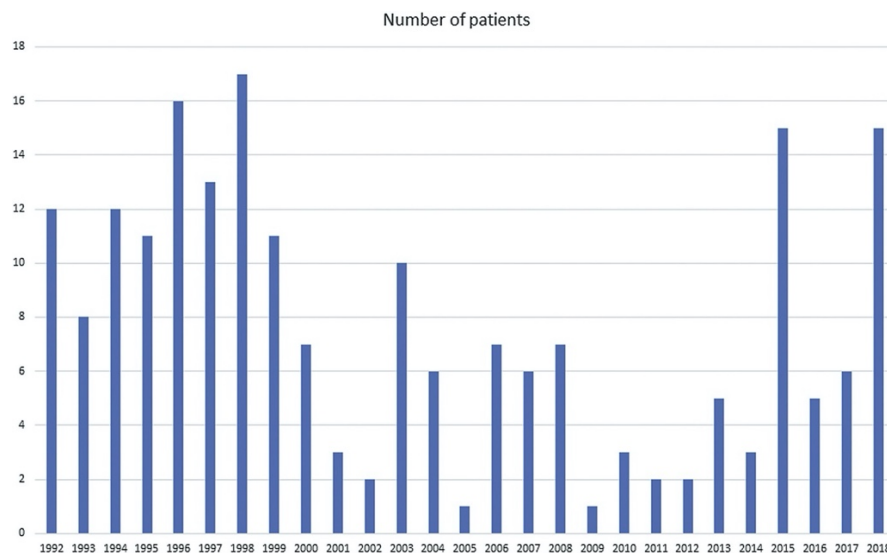
Between 1992 and 2018, 3 methods of scrotal reconstruction were employed in our center:

1. In the method described by Hage et al,<sup>6,7</sup> a reversed V-incision is made in both labia majora. A dorsally based skin flap is created, and testicular prostheses are immediately implanted if space and skin laxity are sufficient to do so. Subsequently, the skin is closed in a Y-like manner. When there is insufficient space to do so, testicular prostheses are placed in a later stage.
2. Dorsally based reversed V-shaped bilateral labia majora flaps are closed in the midline to create a scrotum with a less bifid appearance. In a later stage, testicular prostheses may be placed.
3. In the Hoebeke method, 2 cranially based bilateral labia majora flaps are rotated medially and combined with a horseshoe-shaped, bilaterally vascularized prepubic skin flap to create the neoscrotum.<sup>8</sup> In a later stage, testicular prostheses may be placed. This is our current technique for scrotal construction.

**Table 1.** Patient demographics.

Demographic	Value
Total number of included patients	206
Gender affirming surgery reconstruction type, n (%)	
Metoidioplasty	162 (78.6)
With urethral lengthening	155 (75.2)
Without urethral lengthening	7 (3.4)
Phalloplasty	44 (21.4)
With urethral lengthening	28 (13.6)
Without urethral lengthening	16 (7.8)
Scrotoplasty type, n (%)	
According to Hage	112 (54.4)
with direct prosthesis implantation	75 (36.4)
with delayed prosthesis implantation	37 (18.0)
Dorsally-based V-shaped bilateral labia majora flaps	42 (20.4)
According to Hoebeke	52 (25.2)
Age at prosthesis implantation (y), mean $\pm$ SD	33 $\pm$ 9
Body mass index, n (%)	
<20	22 (10.7)
$\geq$ 20 to <25	113 (54.9)
$\geq$ 25 to <30	53 (25.7)
$\geq$ 30	18 (8.7)
Active smoker, n (%)	57 (27.7)
Documented history of drug (ab)use, n (%)	
Alcohol abuse	2 (1.0)
Amphetamines	1 (0.5)
Cannabis	9 (4.4)
Cocaine	2 (1.0)
Intravenous drugs	2 (1.0)
XTC	1 (0.5)
ASA physical status classification, n (%)	
ASA 1	129 (62.6)
ASA 2	73 (35.4)
ASA 3	4 (1.9)
ASA 4	-
Clinical follow-up (y) mean $\pm$ SD	11.5 $\pm$ 8.3

ASA = American Society of Anesthesiologists



**Figure 1.** Number of patients who underwent testicular prosthesis implantation per year.

#### Current Technique for Testicular Prosthesis Implantation

Testicular prosthesis implantation is performed as a secondary procedure after genital GAS. Patients are placed in a supine frog-leg position. The approach is by either a mid-scrotal vertical incision or a horizontal incision at the scrotophallic transition. Two separate pockets are created for the implants. The size of the implanted testicular prostheses depends on the size of the pockets created, which is dependent on neoscrotal size. Rarely the implants require fixation. The pockets are closed separately with soluble sutures, and the wound is closed in 2 layers. Patients are advised not to place any pressure on the scrotum for at least 4 weeks.

#### Follow-Up Protocol

Over the years, different follow-up protocols were followed. Currently, patients are seen at the outpatient clinic 2 and 6 weeks after testicular prosthesis implantation, or earlier if deemed necessary by the patient or caregiver. Most patients, however, are seen more frequently at our outpatient clinic because of regular follow-up appointments that are part of their total surgical care package, such as follow-up appointments after phalloplasty, erectile prosthesis implantation, or secondary (genital) corrections or general urological follow-up appointments.

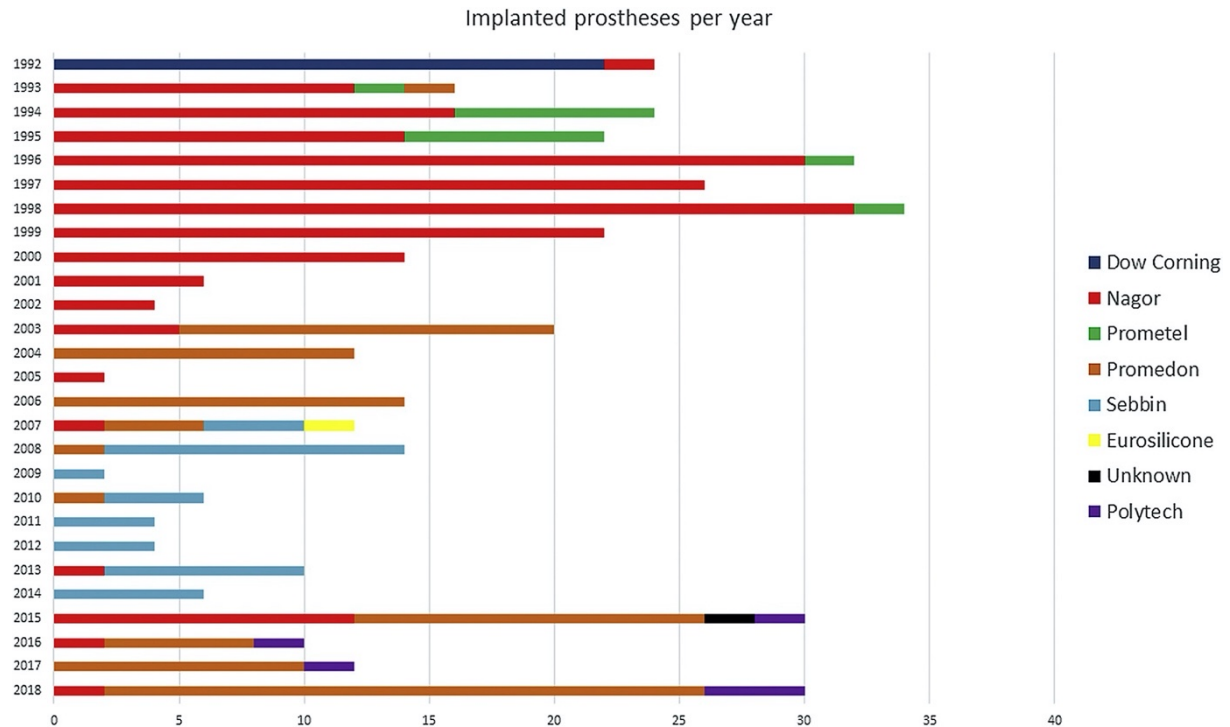
#### Statistical Analyses

All statistical analyses were performed using SPSS Statistics 22 (IBM Corp; Armonk, NY). Continuous non-Gaussian variables are presented as medians and ranges, and continuous Gaussian variables are presented as means and standard deviations. Implant survival outcomes are presented as Kaplan-Meier curves. Risk factors for explantation, infection, extrusion, and dislocation were determined through a multivariate forward logistic regression analysis. Odds ratios (ORs) are presented where appropriate.

**Table 2.** Implanted testicular prostheses characteristics (N = 412)

Prostheses placed	Subtype	n(%)
Dow Corning	Total	22 (5.3%)
	Adult average	8
	Adult large	14
Eurosilicone	Total	2 (0.5%)
	18cc	2
Nagor	Total	205 (49.8%)
	Firm medium	13
	Firm large	50
	Gel-Filled small	24
	Gel-Filled large	90
	Steel (60g)	28
Polytech	Total	10 (2.4%)
	5cc	2
	12cc	3
	21cc	2
Promedon	Total	105 (25.5%)
	Small	75
	Medium	28
	Large	2
Prometel	Total	22 (5.3%)

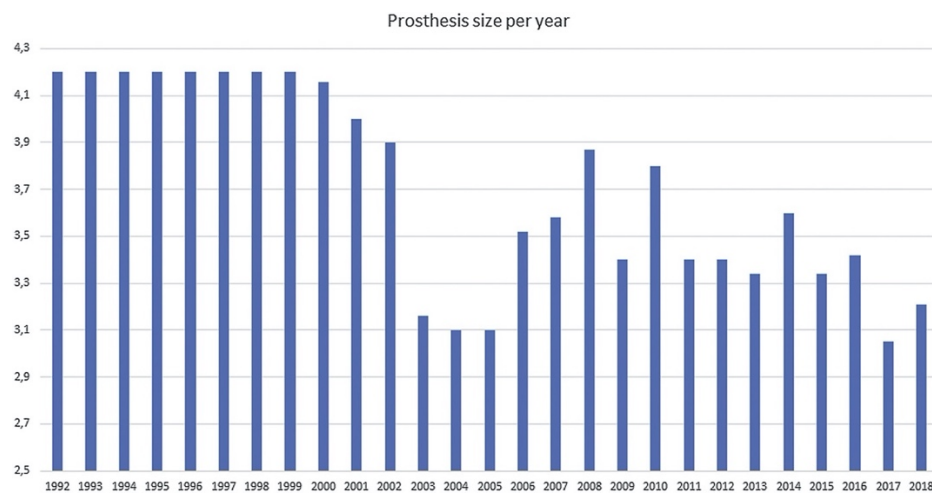
	Adult medium	4
	Adult large	18
Sebbin	Total	44 (10.7%)
	12cc	26
	17cc	16
	27cc	2
Unknown	Total	2 (0.5%)



**Figure 2.** Chronological presentation of implanted testicular prostheses according to manufacturer.

## RESULTS

The data for 206 patients were included in the retrospective analysis. Five patients were deceased at the time of analysis, none as a result of postoperative problems. Patient demographics are presented in Table 1. Some of the patients mentioned below were described earlier, with shorter follow-up. The number of testicular prostheses placed in this population fluctuated over the years, as shown in Figure 1.



**Figure 3.** Mean prosthesis size per year. Before 2001, all prostheses used were over 4 cm long, but smaller prostheses were chosen after that.

**Table 3.** Clinical outcomes of testicular prosthesis implantation in transgender men

Outcome	N (%)			
	All (n=412)	Scrotoplasty according to Hage (n=224)	Dorsally-based V-shaped bilateral labia majora flaps (n=84)	Scrotoplasty according to Hoebeke (n=104)
Explantation, total	53 (12.9)	36 (16.1)	9 (10.7)	8 (7.7)
because of infection	12 (2.9)	7 (3.1)	2 (2.4)	3 (2.9)
because of extrusion	29 (7.0)	19 (8.5)	6 (7.1)	4 (3.8)
because of discomfort	4 (1.0)	3 (1.3)	-	1 (1.0)
because of leakage	4 (1.0)	4 (1.8)	-	-
because of urethral problems*	4 (1.0)	3 (1.3)	1 (1.2)	-
Dislocation, for which relocalization was required	60 (14.6)	45 (20.1)	9 (10.7)	6 (5.8)

\*Urethral problems included leakage of urine through a neourethral fistula to the augmented scrotum (n 1/4 2) and external urethral compression of the prosthesis (n = 2).

### Implanted Testicular Prostheses

A total of 412 testicular prostheses were implanted. Manufacturers included Dow Corning (Midland, MI), Eurosilicone (Apt, France), Nagor (Glasgow, UK), Polytech (Dieburg, Germany), Promedon (Cordoba, Argentina), Prometel (Bornel, France), and Sebbin (Boissy-l'Aillier, France). An overview of the implanted prostheses is presented in Table 2 and Figure 2. A decrease in implant size was observed over the years (Figure 3).

### Postoperative Complications

Implant explantation predominantly occurred in the first postoperative months. In 43 patients (20.8%), one or both prostheses were explanted due to infection, extrusion, discomfort, prosthesis leakage, or urethral problems (Table 3). Explantation of one prosthesis occurred in 36 patients (17.5%) and explantation of both prostheses in 7 patients (3.4%). With regard to the scrotoplasty technique used most prominently today (scrotoplasty according to Hoebeke), explantation of one or both prostheses occurred in 6 of 52 patients (11.5%). A total of 53 out of 412 testicular prostheses (12.9%) were explanted due to infection, extrusion, discomfort, prosthesis leakage, or urethral problems (Table 3). Urethral problems included leakage of urine through a neourethral fistula to the augmented scrotum (n 1/4 2) and external urethral compression of the prosthesis (n 1/4 2). Prosthesis rupture or leakage due to local trauma occurred in 4 patients (1.9%), some of whom were described earlier.<sup>10</sup>

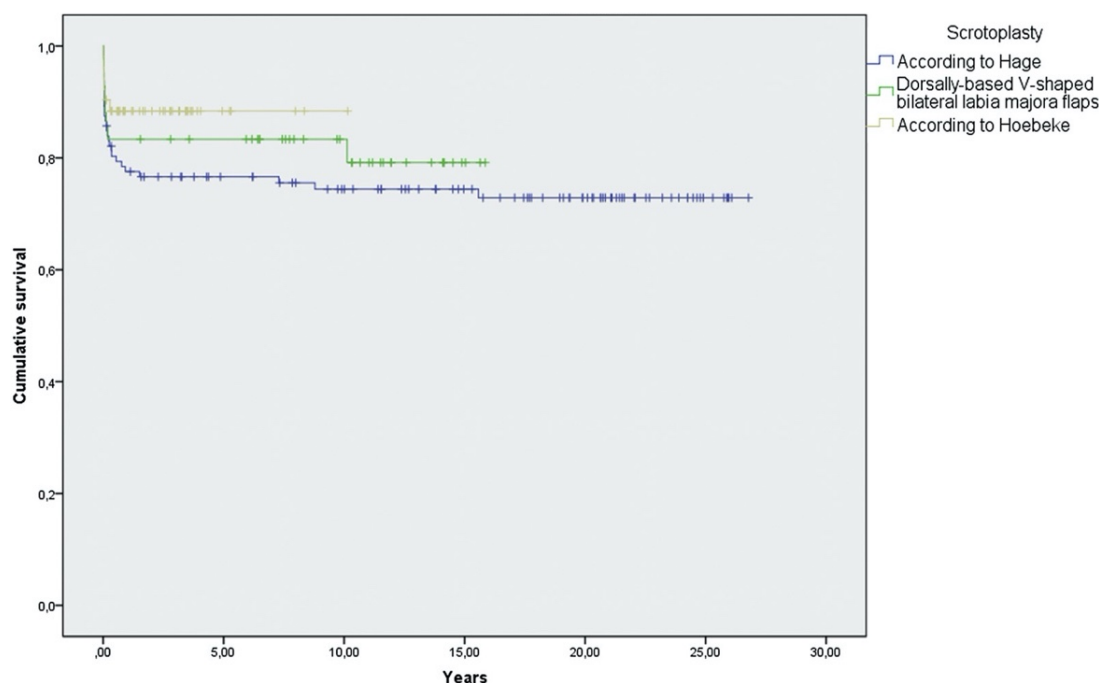
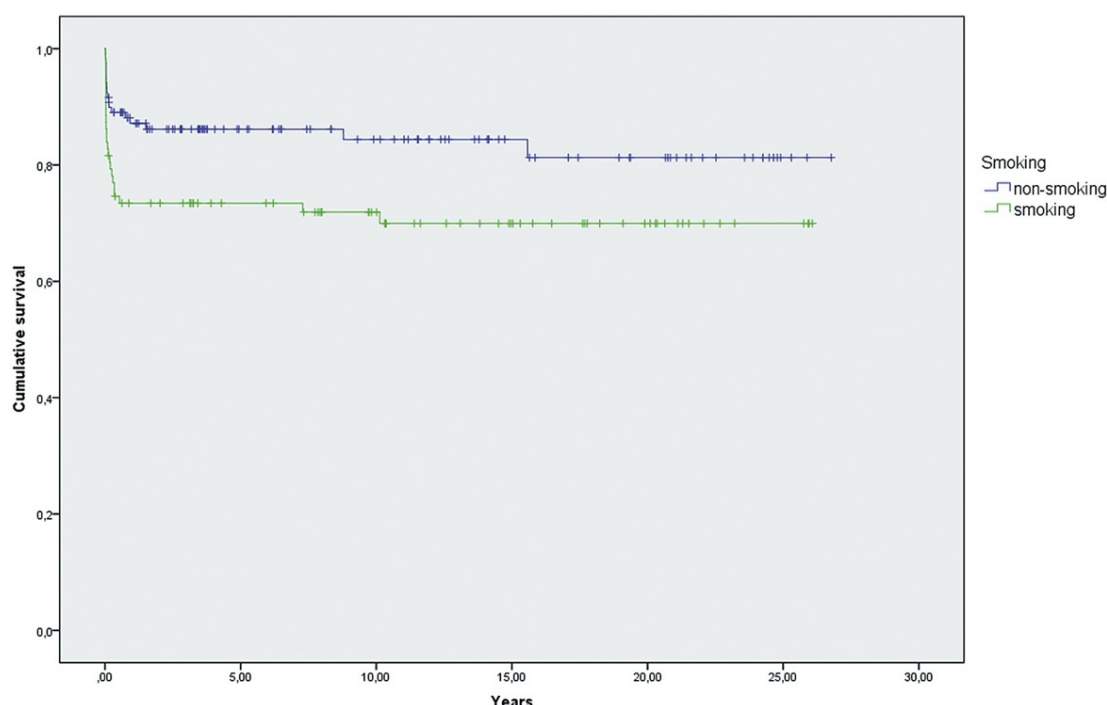


Figure 4. Survival of both testicular prostheses implanted per scrotoplasty variant. The y-axis is the fraction of patients with both primarily implanted testicular prostheses present.



**Figure 5.** Survival of both testicular prostheses implanted for patients with and without a documented history of smoking. The y-axis is the fraction of patients with both primarily implanted testicular prostheses present.

#### Risk Factors Regarding Surgical Complications

As determined by multivariate forward logistic regression analysis, a history of smoking was a risk factor for explantation due to infection ( $P = .003$ ; OR, 7.6; 95% CI, 1.6e35.6) and prosthesis explantation in general ( $P = 1/4 .003$ ; OR, 2.9; 95% CI, 1.4e5.8). The type of scrotoplasty was a risk factor for prosthesis dislocation, for which the technique according to Hage was most prone ( $P < .001$ ; OR, 3.4; 95% CI, 1.7e6.7) (Figures 4 and 5).

#### DISCUSSION

In this article, we described the surgical outcomes of neo- scrotal augmentation by testicular prosthesis implantation in transgender men. Implant explantation was predominantly observed in the first postoperative months. In 43 patients (20.8%), one or both prostheses were explanted due to infection, extrusion, discomfort, prosthesis leakage, or urethral problems. With regard to the scrotoplasty technique currently used most frequently (scrotoplasty according to Hoebeke), explantation occurred in 6 of 52 patients (11.5%). A history of smoking was a risk factor for postoperative infections and prosthesis explantation. In the current literature, explantation rates range from 0.6% to 30% (Table 4).<sup>9,11-15</sup> All studies on this subject are of a retrospective design, and surgical outcomes of testicular prosthesis implantation are not the primary outcome in all. Most studies focus on testicular prosthesis implantation in the labia majora, and other scrotoplasty techniques are not described. Surprisingly little is published on this subject, which highlights the need for better evaluation of this procedure. Our data suggest that testicular prosthesis implantation is a safe procedure with acceptable complication rates, which can be performed in an outpatient setting and in combination with other surgical (genital) procedures. Care should be taken during this procedure, particularly when creating the pockets and choosing the size of the implant. Proper dissection of the pockets with respect to size and position may limit chances of prosthesis dislocation.

The type of scrotoplasty performed was a risk factor for prosthesis dislocation, for which implantation of testicular prostheses in the labia was most prone. At our center, there was a shift from immediate implantation to delayed implantation. Given current data, no conclusions can be drawn on which is better. Because our scrotoplasty technique has changed and requires more tissue dissection, which theoretically results in higher percentages of wound problems such as dehiscence, testicular prostheses are now implanted at least 6 months after genital GAS.

Scrotoplasty can be performed in multiple ways. The current literature mainly focuses on surgical scrotoplasty techniques and complications. Little is known about the effect of different surgical approaches of scrotoplasty and neoscrotal augmentation on patient-reported quality of life and (genital) body image. When it comes to genital body image, it seems likely that scrotoplasty has a positive effect on the distress experienced from genitalia.

In cis men, it is known that orchidectomy influences feelings of esteem and masculinity, causing men to opt for implantation of testicular implants. Satisfaction with testicular implants after radical orchiectomy is high with regard to size, weight, texture shape, position, and comfort level.<sup>17,18</sup> Little is known about the influence of neoscrotal augmentation with testicular prostheses on masculinity and gender dysphoria in transgender men, and this may be subject for further research.

Although the number of transgender people who seek gender affirmation treatment has increased internationally, at our institution this trend is not reflected in the number of implanted testicular prostheses. Possible explanations for this are that, with new scrotoplasty techniques, a certain degree of neoscrotal augmentation is achieved with autologous material and a testicular implant may not add to the feeling



of masculinity. During the metoidioplasty or phalloplasty procedure, local adipocutaneous pedicled flaps, such as described by Hoebeke, are often sufficient to create enough scrotal volume. If this is not the case, extra volume may be obtained with pedicled pubic or labial fat flaps or later neoscrotal fat grafting.

Strengths of this study include the number of patients, long clinical follow-up time, and completeness of the data. Weaknesses of this study include its retrospective nature and the high variability of prostheses and surgical techniques used. This, however, is a reflection of clinical reality. Although clinical outcome is important, patient-reported outcome measures are not a part of this study.

Table 4. Overview of literature on surgical outcomes of testicular prosthesis implantation in transgender men.

Author	Year	n	Genital reconstruction	Testicular prostheses	Scrotal reconstruction	Testicular prosthesis complications	Follow-up
Noe et al <sup>11</sup>	1978	10	Pedicled abdominal flap	NR	Labia majora fusion (n=5) or testicular implantation in labia majora (n=5)	N=6 (60%) incurred an infection with resultant loss of the implants in 3 patients	NR
Hage and van Turnhout <sup>9</sup>	2006	70	Metoidioplasty	NR	According to Hage and van Turnhout	N=22 (31.4%) Explantation not further specified N=34 (48.6%) Prosthesis dislocation	median 8 y (range 4.5-11.7)
Schaff and Papadopoulos <sup>12</sup>	2009	37	Free sensate and pre-laminated os-teofasciocutaneous flaps	Mentor medium	Testicular implantation in labia majora	N=1 (2.7%) testicle prosthesis explantation due to infection	Mean 13 mo (range 11-17)
Djordjevic and Bizic <sup>13</sup>	2013	207	Metoidioplasty	NR	Testicular implantation in labia majora	N=4 (1.9%) Testicular implant rejection N=14 (6.8%) Implant dislocation	median 39 mo (range 12-118)
Kuehhas et al <sup>14</sup>	2015	48	Metoidioplasty	NR	NR	N=12 (25%) Prosthesis infection	Mean 49 mo
Stojanovic et al <sup>15</sup>	2017	473	Metoidioplasty	NR	Testicular implantation in labia majora	N=2 (0.4%) testicular implant rejection N=1 (0.2%) testicular implant displacement	Mean 44 mo (range 10-92)

NR Not reported

## CONCLUSION

Over the years, scrotoplasty techniques and testicular prostheses preferences have changed. Explantation rates have dropped over the last decade, but the risk for the individual patient for testicular implant explantation is still approximately 10%. To date, surprisingly little has been published on this subject. A history of smoking is a predictor for negative surgical outcome.

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## Chapter 6

### A retrospective cohort study on surgical outcomes of penile prosthesis implantation surgery in transgender men after phalloplasty.

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## ABSTRACT

**OBJECTIVES:** To assess surgical outcomes of penile prosthesis implantation in transgender men who underwent phalloplasty.

**PATIENTS AND METHODS:** Transgender men who underwent penile prosthesis implantation after phalloplasty between January 1989 and September 2018 were retrospectively identified. A chart study was performed recording patient demographics, perioperative complications and reoperations.

**RESULTS:** A total of 32 patients were identified: 22 underwent free radial forearm flap (FRFF), 5 anterolateral thigh (ALT), 4 ALT/FRFF and 1 fibular flap phalloplasty. The median age at prosthesis implantation was 36 (range 21-59) years, the mean BMI 25.9±4.0 kg/m<sup>2</sup>. At first implantation, 16 inflatable (AMS Dynaflex (n=13), AMS Ambicor (n=3)) and 16 malleable (Coloplast genesis (n=14), AMS Spectra (n=2)) prostheses were placed. Of these, 5 (16%) were removed/replaced because of infection, 2 (6%) because of leakage, 2 because of extrusion, 2 because of dislocation, 2 because of dysfunction and 1 (3%) because of pain. The postoperative course was completely uneventful in 10 (31.3%) patients. Of all implanted prostheses, including revision procedures (n=45), 21 (44%) were surgically replaced or removed.

**CONCLUSION:** Prosthesis explantation, replacement or revision surgery occurs frequently after penile prosthesis implantation. Patients need to be well-informed preoperatively on these complication rates.

## INTRODUCTION

Genital gender affirming surgery in transgender men includes metoidioplasty and phalloplasty. An important reason for choosing the phalloplasty procedure over metoidioplasty, is the wish to engage in penetrative sexual intercourse. Multiple surgical techniques can be utilized for phalloplasty surgery. The most commonly performed procedure is the free radial forearm flap (FRFF) phalloplasty.[1-3] Several other flaps can be used, such as the abdominal flap, the (pedicled) anterolateral thigh (ALT) flap, latissimus dorsi (LD) flap, the superficial circumflex iliac artery (SCIP) flap and the free fibula flap (with or without bonegraft).[4-8] A combination of flaps has also been described.[9-11] In phalloplasty surgery, an aesthetically pleasing phallus with the possibility of voiding in standing position can often be achieved. However, the neophallus could lack the rigidity that is needed for penetrative sexual intercourse.

Nowadays, patients deemed eligible for erectile prosthesis implantation are typically at least one year after phalloplasty surgery, have no urethral problems, are not awaiting secondary corrections of the phalloplasty or scrotoplasty and have a neophallus that is sensate, to an extent that protective sensibility is present.

The aim of this study was to assess the surgical outcomes of erectile prosthesis implantation in transgender men who underwent phalloplasty.

## PATIENTS AND METHODS

### Retrospective chart study

In the period January 1988 to September 2017, a total of 170 patients underwent phalloplasty at our institution. All transgender men who underwent erectile prosthesis implantation after phalloplasty, from January 1989 until September 2018, were retrospectively identified from our hospital registry. A single-center retrospective chart review was performed, recording patient demographics (type of phalloplasty procedure performed, other medical and surgical history, comorbidity, age at surgery, body mass index (BMI) and use of medication, alcohol, nicotine and/or drugs), peri-operative characteristics (date of surgery, prosthesis characteristics, surgical technique, surgery duration, length of hospitalization), intra- and postoperative complications (intra-operative complications, short-term postoperative complications, such as infections, bleeding, necrosis and prosthesis-related complications) and reoperations.

**Table 1.** patients demographics

Total patients, n	32
Median age at phalloplasty, y (range)	32 (19-57)
Phalloplasty type, n (%)	
FRFF	22 (68.8%)
ALT	5 (15.6%)
ALT + FRFF	4 (12.5%)
Fibula	1 (3.1%)
Median age at prosthesis implantation, y (range)	36 (21-59)
Mean BMI, kg/m <sup>2</sup> ± SD	25.9 ± 4.0
History of smoking, n (%)	16 (50%)
Prosthesis placement, n (%)	
Immediate during phalloplasty	2 (6.3%)
Delayed	30 (93.8%)
Originally implanted prosthesis, n (%)	
Total	32 (100%)
Inflatable	
AMS Dynaflex	13 (40.6%)
AMS Ambicor	3 (9.4%)
Malleable	
AMS Spectra	2 (6.3%)
Coloplast Genesis	14 (43.8%)
All implanted prostheses, including revision procedures, n (%)	
Total	45 (100%)
Inflatable	
AMS Dynaflex	18 (40%)
AMS Ambicor	4 (8.9%)
Malleable	
AMS Spectra	2 (4.4%)
Coloplast Genesis	21 (46.7%)

### Current operative technique

Over time, the surgical technique for penile prosthesis implantation has changed in our center and worldwide. Here we describe the current technique, in which a Coloplast Genesis prosthesis is implanted which is covered by a vascular prosthesis (Dacron). The skin in the genital region is shaved after intubation. Subsequently, the genital region is scrubbed with soap and meticulous disinfection is performed with

chlorhexidine and povidone-iodine. A second-generation cephalosporin is administered intravenously as antibiotic prophylaxis. In patients who underwent phalloplasty with urethral lengthening, a transurethral catheter is placed.

In case of implantation of two cylinders, two parascrotal incision are made. When placing only one cylinder, one parascrotal incision is made, or an incision at the dorsal base of the phallus. The ventral and proximal part of the ramus superior is freed from surrounding tissue. Two non-resorbable Prolene 2.0 sutures are placed through the periosteum, to enable firm fixation of the implant base later in the procedure. The phallus is dilated to approximately one centimeter underneath the top of the phallus. It is important to leave a sufficient amount of subcutaneous fat between the implant and the top of the phallus to prevent implant erosion. After single-flap phalloplasty, dilatation of the phallus is performed in the middle of the shaft. After double-flap phalloplasty, the location of the prosthesis is easily dissected between the two flaps. The length of the cavity is measured with the Furlow inserter.

The measured length and width of the phallus are decisive for the size of the implants and these are trimmed according to the measured length. A rear tip extender is not necessary. The penile prosthesis and vascular prosthesis (Dacron) are rinsed with a rifampicin/gentamicin solution. The base of the prosthesis is covered by the vascular prosthesis, and fixed to the pubic bone with non-resorbable sutures. At the end of the procedure, skin quality and tissue viability is checked. Dermis and subcutaneous tissues are approximated and epidermis is closed with resorbable sutures.

### Patient satisfaction

All consenting patients, with a prosthesis in place, were asked to complete a combined questionnaire. The questionnaire consisted of the Cantril's Ladder of Life Scale (a single-item indicator of well-being, in which a patient rates life satisfaction between 0 and 10) and a self-created questionnaire with seven questions pertaining to sexuality and satisfaction with the operative result. Patients were asked to grade their satisfaction on a Likert scale from 0 (not satisfied) to 5 (totally satisfied). Additionally, patients were asked to grade the operative end result on a scale from 1 to 10.

### Statistical analysis

IBM SPSS software Version 20 for Windows (IBM Corp., Armonk, N.Y.) was used for all statistical analyses. For patient demographics, Gaussian continuous variables were presented as means with standard deviations, non-Gaussian continuous variables were presented as medians with ranges and categorical variables were presented as frequencies and percentages.

### Ethical statement

This retrospective chart study was exempt from institutional review board approval. The study on patient-reported outcomes was approved by our local medical ethical committee (METC, reference number 2018625). All photographed patients provided written informed consent for use of the photographic material. All included patients provided written informed consent for retrospective use of their medical data.

## RESULTS

### Patient demographics

From January 1989 until September 2018, a total of 32 patients were retrospectively identified that underwent penile prosthesis implantation. Patient demographics are presented in Table 1. Twenty-two patients underwent FRFF (for an example, Figure 1), five ALT four ALT/FRFF and one fibular flap phalloplasty. Two patients underwent penile prosthesis implantation in the same session as the phalloplasty procedure.

### Retrospective chart study

A total of 45 prostheses were implanted in 32 transgender men. The median postoperative follow-up was 4.6 years (range 0.4-23.9). Of 32 originally implanted prostheses, 16 were surgically removed or replaced after a median of 1.1 years (range 7 days – 18.8 years). Five (15.6%) were explanted because of infection. Of all implanted prostheses (n=45), 21 (44%) were surgically removed or replaced. Eight (17.8%) were explanted because of infection. The postoperative course was uneventful in 10 patients. At last follow-up, 24 (75%) patients had a penile prosthesis in place, while eight (25%) did not. An overview of postoperative complications is presented in Table 2. Individual cases are presented in Table 3.

**Table 2.** Overview of postoperative complications

Originally	Implanted	Prosthesis	
Total,	n	(%)	
Total,			32 (100%)
Surgically removed or replaced, n (%)			16 (50%)
Infection, n (%)			5 (15.6%)
Leakage, n (%)			2 (6.3%)
Extrusion, n (%)			2 (6.3%)
Low-grade infection, n (%)			2 (6.3%)
Dislocation, n (%)			2 (6.3%)
Disfunction, n (%)			2 (6.3%)
Pain, n (%)			1 (3.1%)

All implanted prostheses (including revision procedures)			
Total,	n	(%)	45 (100%)
Surgically removed or replaced, n (%)			21 (44%)
Infection,	n	(%)	8 (17.8%)
Leakage,	n	(%)	3 (6.7%)
Extrusion, n (%)			3 (6.7%)
Low-grade infection, n (%)			2 (4.4%)
Dislocation, n (%)			2 (4.4%)
Disfunction, n (%)			2 (4.4%)
Pain, n (%)			1 (2.2%)

**Table 3.** Overview of included patients and postoperative complications

Case #	Age at im-plantation	Phallo-plasty	With ure-thral lenghten-ing?	Time after Phallo-plasty (years)	History of smok-ing	BMI	Type prosthe-sis origi-nally im-planted	Postoperative complica-tions and reoperations	Prosthe-sis in place at last FU?	Clinical FU (years)
1	36	FRFF	Yes	1,8	Yes	22,6	AMS Dynaflex	+9m Prosthesis disloca-tion, for which adhesioly-sis and surgical refixation +3.5y Prosthesis leakage, for which new prosthesis implantation AMS Dynaflex +13.2y Prosthesis leak-age, for which new pros-thesis implantation Coloplast Genesis +16.3y Prosthesis infec-tion, for which prosthesis explantation	No	23,3
2	42	FRFF	Yes	3,2	Yes	33,6	AMS Dynaflex	+18.5y Prosthesis dys-function, for which revi-sion was planned. Intra-operatively was a low-grade infection ob-served, so only explanta-tion was performed. +19.0y New prosthesis placement (Coloplast Genesis) +19.2y Prosthesis infec-tion, for which prosthesis explantation	No	19,6
3	43	FRFF	Yes	19,0	Yes	31,1	Coloplast Genesis	+1.9y Prosthesis extru-sion, for which prosthe-sis explantation +4.5y New prosthesis placement (AMS Dynaflex) +4.8y Prosthesis extru-sion, for which prosthe-sis explantation	No	4,8
4	24	FRFF	Yes	0,0	Yes	21,0	AMS Dynaflex	+8m Prosthesis infection, for which prosthesis ex-plantation	Yes	23,9

								+1.2y New prosthesis placement (Coloplast Genesis)		
5	39	FRFF	Yes	0,0	No	19,0	AMS Dynaflex	+4.0y Prosthesis leakage, for which new prosthesis implantation AMS Dynaflex	Yes	4,5
6	31	FRFF	Yes	1,8	No	26,3	AMS Dynaflex	None	Yes	8,5
7	30	FRFF	Yes	2,2	Yes	28,0	AMS Dynaflex	+9.7y Prosthesis dysfunction, patient did not wish further surgery	Yes	18,3
8	36	FRFF	Yes	1,4	Yes	23,2	AMS Dynaflex	None	Yes	6,4
9	51	FRFF	Yes	2,2	No	22,3	AMS Dynaflex	None	Yes	18,2
10	41	FRFF	Yes	1,1	No	23,9	AMS Dynaflex	None	Yes	2,1
11	30	FRFF	Yes	10,3	Yes	35,5	AMS Ambicor	+2m Infection and leakage of prosthesis, for which prosthesis explantation	No	10,3
12	50	FRFF	Yes	1,0	No	28,0	AMS Dynaflex	+7d Prosthesis extrusion, for which prosthesis explantation +2.4y New prosthesis placement (AMS Dynaflex)	Yes	4,0
13	25	FRFF	Yes	2,2	Yes	22,7	Coloplast Genesis	+7m Prosthesis infection, for which prosthesis explantation	No	0,6
14	34	FRFF	Yes	3,3	Yes	27,0	Coloplast Genesis	None	Yes	0,4
15	30	FRFF	Yes	3,0	Yes	29,2	AMS Dynaflex	+14d Prosthesis infection, for which prosthesis explantation +6m New prosthesis placement (AMS Dynaflex)	Yes	21,3
16	23	FRFF	No	2,8	No	24,2	Coloplast Genesis	None	Yes	2,8
17	42	FRFF	Yes	5,1	No	28,7	AMS Spectra	None	Yes	6,0
18	43	FRFF	Yes	2,4	Yes	32,7	AMS Ambicor	None	Yes	1,5
19	47	FRFF	Yes	2,0	Yes	22,4	Coloplast Genesis	+1.2y Prosthesis dislocation, for which new prosthesis implantation Coloplast Genesis	Yes	2,1
20	56	FRFF	Yes	14,0	No	23,7	AMS Ambicor	+8.4y Prosthesis dysfunction, for which new prosthesis implantation AMS Ambicor +10.5y Pump dislocation, for which surgical refixation	Yes	11,3
21	42	FRFF	Yes	3,2	Yes	33,6	AMS Dynaflex	+18.8y Low-grade prosthesis infection, for which prosthesis explantation	No	19,6

								+19.0y New prosthesis placement (Coloplast Genesis)		
								+19.2y Prosthesis infection, for which prosthesis explantation		
22	21	FRFF	Yes	1,6	No	23,6	Coloplast Genesis	+1y Prosthesis dislocation, for which surgical refixation	Yes	1,0
23	43	ALT	No	3,2	Yes	25,3	AMS Spectra	+2.4y Prosthesis dislocation, for which surgical refixation	Yes	5,7
24	24	ALT	No	2,1	No	27,1	Coloplast Genesis	+8m Prosthesis dislocation, for which surgical refixation	Yes	1,6
25	49	ALT	No	3,6	Yes	23,1	Coloplast Genesis	1.9y Prosthesis dysfunction, for which new prosthesis implantation Coloplast Genesis	Yes	2,0
26	28	ALT	Yes	2,5	No	21,7	Coloplast Genesis	+10m Prosthesis dislocation, for which new prosthesis implantation Coloplast Genesis	Yes	1,2
27	29	ALT	Yes	1,7	No	23,0	Coloplast Genesis	None	Yes	0,7
28	59	ALT+FRFF	Yes	1,5	No	22,6	Coloplast Genesis	+5m Prosthesis dislocation, for which surgical refixation	Yes	0,7
29	42	ALT+FRFF	Yes	1,6	Yes	26,8	Coloplast Genesis	+4m Prosthesis dislocation, for which surgical refixation	Yes	3,8
30	36	ALT+FRFF	Yes	5,8	No	27,3	Coloplast Genesis	+12d Surgical site infection, for which oral antibiotics +11m Penile pain when using the prosthesis, for which explantation	No	1,1
31	26	ALT+FRFF	Yes	4,5	No	26,3	Coloplast Genesis	+3.8m Prosthesis infection, for which prosthesis explantation	No	0,5
32	24	Fibula	Yes	2,1	No	22,1	AMS Dynaflex	None	Yes	21,1

ALT, anterolateral thigh flap; BMI, body mass index; FRFF, free radial forearm flap; FU, follow-up

#### Patient satisfaction

A total of 14 out of a possible 24 (58%) patients with a penile prosthesis in place completed the questionnaire. They rated their life satisfaction  $7.8 \pm 1.3$  out of 10. An overview of questionnaire outcome is presented in Supplementary Table 1.

#### DISCUSSION

Genital gender affirming surgery alters feelings of gender dysphoria. In phalloplasty surgery, implanting a penile prosthesis is often the last surgical step in the transition process. In this article, we reported on 32 transgender men who underwent penile prosthesis implantation between 1989

and September 2018. At last follow-up, 24 (75%) patients had a penile prosthesis in place. Revision surgery was performed in 21 (65.6%) patients. Of a total of 45 implanted prostheses, eight were removed because of infection. A total of 14 out of a possible 24 (58%) patients with a penile prosthesis in place completed the questionnaire. They rated their life satisfaction  $7.8 \pm 1.3$  out of 10.

An overview of literature published on the subject is presented in Supplementary Table 2. All published research is of retrospective nature. Current research on clinical outcomes of penile prosthesis implantation in transgender men report predominantly on inflatable prostheses after FRFF phalloplasty. Most literature focusses on hydraulic prostheses, but a wide array of prostheses and phalloplasty subtypes are reported. In the larger recent studies, explantation due to infection was described to occur in 6-12% of procedures, with varying follow-up

times. In our series, 17.8% of prostheses were explanted due to infection. Why this is higher than described in literature is probably mostly a result of the inclusion period of our study, which dates back to 1989.

In our institution, patients can choose between hydraulic and malleable devices. Current literature on penile prostheses in transgender men primarily focusses on the uses of hydraulic devices. In general, inflatable prostheses are considered superior to malleable prostheses, because it produces rigidity and flaccidity which resembles the biological penis.[19] However, patient-factors, patient- preferences and surgeon-pref-erences may greatly influence the choice of prosthesis. Theoretically, inflatable prostheses are at higher risk of material fatigue, which may negatively influence the life duration of these prostheses. On the other hand, malleable prostheses may cause a more constant pressure on the surrounding tissue, which may consequently lead to a higher risk of erosion and subsequent prosthesis extrusion. High numbers of complications and secondary procedures are recorded after penile prosthesis implantation in transgender men after phalloplasty. Still, transgender men are willing to undergo these procedures, giving the impression that not the number of surgeries but the end result deter-mines patient satisfaction and quality of life.

As mentioned before, a penile prosthesis is implanted if patients are at least one year after phalloplasty, protective sensibility of the ne-ophallus is present, and patients are not waiting for any type of surgery of the phallus and/or scrotum. The time frame of one year is chosen, because that is considered the time of recovery of the sensibility of the phallus. It is postulated that sensibility of the phallus helps to protect a patient from extrusion of the implanted penile prosthesis. Less sensibility of the phallus is considered a contraindication for implantation of the penile prosthesis. However, no data is available on this relation.

Genital gender affirming surgery is increasingly being performed as a single stage procedure. For example, (1) removal of internal and/or external female genitalia, (2) free or pedicled flap phalloplasty, (3) urethral lengthening, (4) scrotoplasty and (5) insertion of testicular im-plants, are performed in a single session in certain centers.[20,21] Historically, immediate prosthesis implantation during the phalloplasty procedure was performed twice in our series. In current literature and in our center, this is now no longer standard practice. Postoperative wound dehiscence, which at a minor extent can be expected, and/or infection may lead to early prosthesis infection. Therefore, prosthesis implantation is now no longer performed as 'immediate' procedure. Currently, patients are deemed eligible for prosthesis implantation if the phalloplasty procedure was a minimum of one year before and after recovery of the sensibility of the phallus.

In our center, phalloplasty surgery was traditionally performed using FRFF or abdominal flaps. With the increase of surgical experience and expertise, now a wider range of flaps is available for this surgical procedure, including ALT flaps, SCIP flaps and a combination of flaps. Which flap constitutes the perfect acceptor site for a penile prosthesis is unknown. In literature, it is noted that more complications arise after implantation of a hydraulic device in infra-umbilical pubic flaps when compared to the FRFF, probably because multiple cylinders are neces-sary. For malleable prostheses, there are no data available. It is noteworthy that current literature focusses primarily on prosthesis implan-tation in FRFF or suprapubic/abdominal flaps.

Until recently, penile prostheses used in the transgender population were designed for use in the non-transgender population. In the last years, several prostheses designed for the transgender population were put on market (e.g. Zephyr ZSI 100 FTM Malleable and Zephyr ZSI 475 FTM Inflatable penile prosthesis).[18,19] It will be interesting to review the surgical outcomes and patient- reported outcomes after implantation of these prostheses in larger patient groups.

One of the strengths of this study is that it focuses on a subject which is scarcely reported on, but may be of significant importance to the transgender population. A second strength is that this research provides data on malleable prosthesis implantation instead of inflatable prosthesis implantation, a group that is sometimes neglected in literature. Another strength is that a long clinical follow-up time is reported. Weaknesses of the study comprise the retrospective nature and the small size of the studied population. Quality of life and sexual function outcomes are reported in this study, but standardized, validated questionnaires are lacking for this specific population. Preoperative data on sexual health and life satisfaction was not available.

## CONCLUSION

Prosthesis explantation, replacement or revision surgery occurs frequently after penile prosthesis implantation. Patients need to be informed preoperatively on these complication rates.

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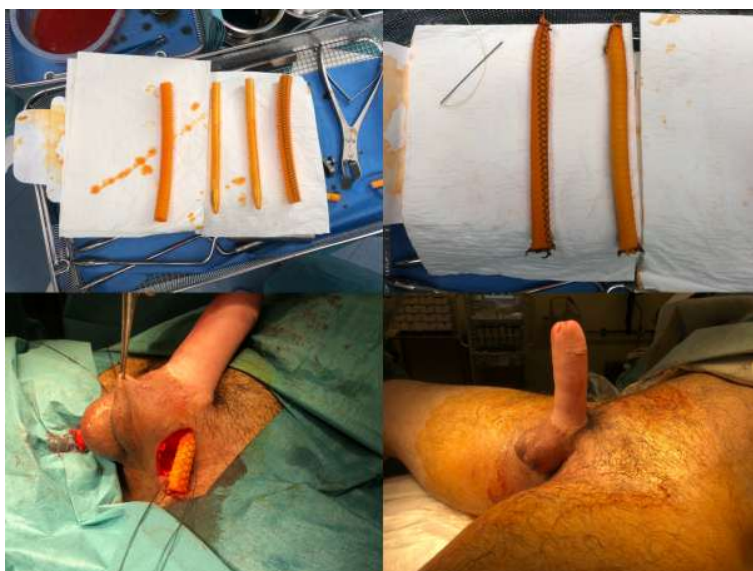
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#### FIGURE LEGENDS

Figure 1. Implantation of Coloplast Genesis non-inflatable, semi-rigid penile implant in a transgender male after free radial forearm flap phalloplasty. Left upper. Coloplast Genesis and Dacron prostheses. Right upper. The Coloplast prosthesis is inserted into the Dacron sock. Left lower. Fixation to the pubic bone. Right lower. Postoperative result.



## Chapter 7

### Surgical Experience and Outcomes of Implantation of the ZSI 100 FtM Malleable Penile Implant in Transgender Men After Phalloplasty

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#### ABSTRACT

**Introduction:** After free or pedicled flap phalloplasty, many transgender men need penile prosthesis implantation to successfully engage in penetrative sexual intercourse. Postoperative complications occur frequently. There is a choice between inflatable and malleable penile prostheses. Until recently, no prostheses were designed specifically for this population.

**Aim:** The aim of this study was to describe our preliminary experience with, and surgical outcomes of, implantation of the ZSI 100 FtM Malleable Penile Implant after phalloplasty in transgender men.

**Methods:** A retrospective chart study was conducted on surgical characteristics and postoperative complications after implantation of the ZSI Malleable Penile Implant in transgender men in 3 European centers for genital transgender surgery in Amsterdam, Stockholm, and Reykjavik.

**Main Outcome Measure:** The main outcomes measures were surgical outcome, complications, and reason of implant failure.

**Results:** 25 patients were retrospectively identified, with a mean age of  $36 \pm 9$  years at implantation. The mean time between prosthesis implantation and phalloplasty was  $3.6 \pm 2.5$  years. 10 patients previously underwent free radial forearm flap phalloplasty, 6 patients had anterolateral thigh flap phalloplasty, 2 patients had superficial circumflex iliac artery perforator phalloplasty, 1 patient had groin flap phalloplasty, and 6 patients underwent combination flap phalloplasty. With a mean follow-up of 6.3 months, prosthesis explantation because of complications was performed in 8 patients (32%), because of infection (n 1/4 3), protrusion (n 1/4 4), or pubic pain (n 1/4 1). In an additional 3 patients, the prosthesis was explanted due to difficulty living with the malleable prosthesis. Of those with the prosthesis in place, 13 of 14 patients (93%) were able to engage in penetrative sexual intercourse.

**Clinical Implications:** The current article provides advantages and disadvantages of this medical device.

**Strength & Limitations:** This is the first study on the ZSI Malleable Penile Implant prostheses in this patient group. It also provides information on the use of malleable prostheses; whereas current literature predominantly focusses on inflatable devices. Limitations comprise the small patient population, short follow-up time, and retrospective nature of the study.

**Conclusion:** Complication rates of the ZSI Malleable Penile Implant prosthesis seem high at the start of the learning curve. Although designed specifically for the transgender community, not all transgender patients will be eligible for this type of prosthesis. Patients need to be well counseled on specific (dis)advantages of the prosthesis.

#### INTRODUCTION

The incidence of transgender people seeking (surgical) care is increasing in The Netherlands, Sweden, and worldwide.<sup>1,2</sup> In transgender men who express the wish for genital gender affirming surgery, metoidioplasty, and free or pedicled flap phalloplasty with or without urethral lengthening are the surgical options. Those undergoing genital gender affirming surgery have to make a choice regarding surgical treatment based on personal preferences and expectations. In those wishing to be able to engage in penetrative sexual intercourse, free or pedicled flap phalloplasty is indicated. Because of a lack of rigidity after phalloplasty, many transgender men need penile prosthesis implantation to successfully engage in penetrative sexual intercourse. Beside this, some transgender men view the absence of a penile implant as a shortcoming, which has a negative influence on the feeling of masculinity and restrains them in seeking sexual relationships.<sup>3</sup>

There is a choice between inflatable and malleable penile prostheses. Until recently, no prostheses were designed specifically for transgender men after phalloplasty. Historically, post-operative complications occur frequently in transgender men undergoing this procedure.<sup>4-6</sup> Recently, Zephyr Surgical Implants (Geneva, Switzerland), introduced 2 types of prostheses specifically designed for use after phalloplasty surgery; a malleable and an inflatable design. First surgical results published on the inflatable 3-piece device are promising.<sup>7</sup> In this study, we describe our first experience with the ZSI Malleable Penile Implant in transgender men after phalloplasty surgery.

#### METHODS

##### Retrospective Chart Study

This is an international collaboration of 2 surgical teams performing surgery in the following centers: Amsterdam University Medical Center (Amsterdam, The Netherlands), Karolinska University Hospital (Stockholm, Sweden) and Landspítali University Hospital (Reykjavik, Iceland). All trans-gender men who underwent free or pedicled flap phalloplasty with subsequent implantation of the ZSI Malleable Penile Implant in the abovementioned centers were retrospectively identified from the hospital registry. A retrospective chart study was conducted, recording patient characteristics (surgical history, phalloplasty type, comorbidities, such as diabetes, hypertension, and being an active smoker or have

a history of smoking), surgical characteristics (preoperative antibiotic protocol, operative procedure, surgical approach, and type of prosthesis placed), postoperative follow-up protocol (postoperative antibiotic protocol and scheduled outpatient visits), and postoperative complications. The standardized Clavien-Dindo classification was used to grade the severity of postoperative complications.

#### **Zephyr Surgical Implant ZSI 100 FTM (D13)**

This malleable implant is a 1-component piece with a realistic shaped removable glans stopper and a 4-hole fixation plate (30 x 25 mm) made of stainless steel and silicone. The diameter is 22 mm in the central part and the length is adjustable from 13-20 cm. A narrow version is also on the market (D13) with a width of 13 mm and maximum length of 23 cm. The length can be adjusted at the distal part of the prosthesis by cutting it to adequate length. It is adjustable by cutting 5 mm by 5 mm. Bendability is accomplished by a silicone and silver cable.

#### **Peri-Operative Protocol**

Before surgery, risks of the surgery are explained at the outpatient consultation. All patients are referred to an experienced sexologist for pre-operative counseling with concern to sexual functioning and postoperative expectations. Penile prosthesis implantation is performed a minimum of 1 year after phalloplasty. Recovery of phallic sensation is preferable, but not mandatory.

All patients are screened by an anesthesiologist according to local protocol. 30 minutes before surgery, a second-generation cephalosporin is administered intravenously. Under general anesthesia, the patient's pubic and genital skin is shaved, scrubbed, and disinfection is performed. Transurethral catheters are placed in patients who underwent phalloplasty with urethral lengthening and are removed the day after surgery. In patients who did not undergo urethral lengthening, no transurethral catheter is placed. Patients receive antibiotics during the first 24 postoperative hours. They are discharged the day after surgery. Scheduled outpatient visits are planned 4-6 weeks after surgery. Patients are advised to wear the phallus upward for 4 weeks after prosthesis implantation.

#### **Surgical Technique**

Before initiating surgery, the genital region is scrubbed with soap and meticulous disinfection is subsequently performed with chlorhexidine and povidone-iodine. Different surgical approaches can be performed. In initial cases, a parascrotal incision was made, whereas in later cases, a dorsal approach, frequently through the old scar at the root of the phalloplasty, was chosen (Figure 1A). This provides excellent access to the pubic bone and penile base. A tunnel is dissected bluntly typically not further than 1 cm to the top of the phallus (Figure 1B). The cavity length is measured with a furrow (Figure 1C). After single flap phalloplasty, the cavity is dissected in the middle. When a free or pedicled flap is used for neo-urethral reconstruction, the cavity is dissected between the 2 flaps. The cavity should not be too subcutaneous, as prosthesis erosion may occur without sufficient tissue coverage.

Subsequently, dissection is performed to the pubic bone. Adequate hemostasis at this point is of importance, because the region will be less easily visualized after fixation of the prosthesis. 2 to 4 non-resorbable monofilament parachute stitches are placed through the pubic periosteum (Figure 1D). These sutures need sufficient grip, as these are the primary fixation points of the prosthesis. Fixation can also be achieved by using bone anchors.

When taken in regard, the neophallic size and the width of the cavity, an appropriate size prosthesis, standard or small (D13) is chosen, based on clinical experience. The prosthesis is taken out of its container in sterile conditions (Figure 1E) and rinsed with rifampicin and gentamycin (Figure 1F). The cavity is measured, and the prosthesis is cut to the proper size. Too long will possibly lead to skin erosion, too small will lead to a droopy distal part of

the penis (similar to a droopy glans) with a possible limitation engaging in penetrative sexual intercourse. The basal prosthesis plate has 4 holes, 1 in each corner, through which fixation sutures are led (Figure 1G). The prosthesis is fixed to the pubic bone (Figure 1H). Long acting local anesthetics are injected at the fixation site. The wound is closed in multiple layers. No drain is left behind.

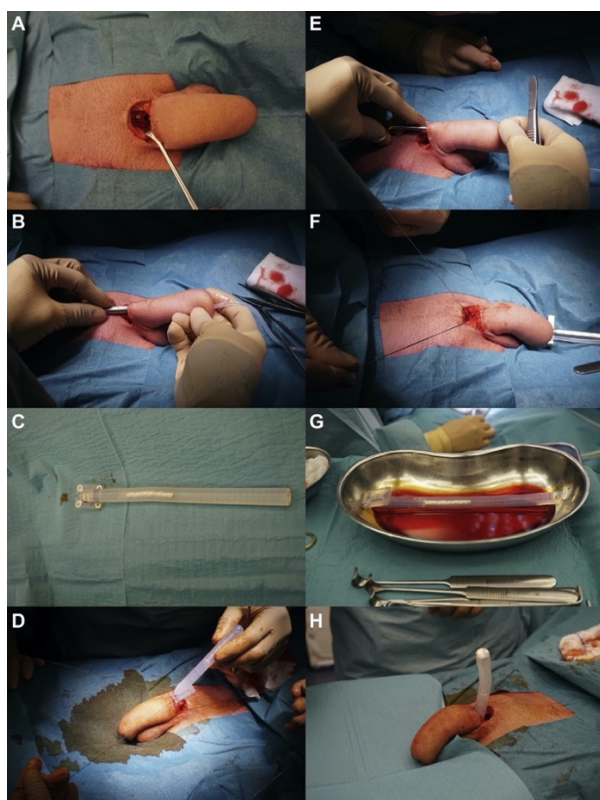


Figure 1. Operative procedure. (A) A dorsal approach through the old scar at the root of the phalloplasty. (B) A neophallic tunnel is dissected bluntly. (C) Cavity length is measured with the furlow. (D) Nonresorbable monofilament parachute stitches are placed through the pubic periosteum. (E) The prosthesis is taken out of its container in sterile conditions. (F) The prosthesis is rinsed with rifampicin and gentamycin. (G) Fixation sutures are led through the four holes in the basal prosthesis plate. (H) The prosthesis is fixed to the pubic bone and subsequently inserted in the cavity. Figure 1 is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org).

#### Ethical Statement

Ethical approval for the study protocol was obtained in all participating centers. All patients provided written consent for use of their anonymized medical data. All photographed patients provided written consent for use and publication of the photographic material.

#### RESULTS

##### Patient Demographics

A total of 25 patients were retrospectively identified, with a mean age of  $36 \pm 9$  years at implantation. The mean time between prosthesis implantation and phalloplasty was  $3.6 \pm 2.5$  years. 10 patients previously underwent free radial forearm flap phalloplasty, 6 patients had anterolateral thigh flap phalloplasty, 2 patients had superficial circumflex iliac artery perforator flap phalloplasty, 1 patient had groin flap phalloplasty, and 6 patients underwent combination flap phalloplasty, which is a phalloplasty procedure using a total of 2 free and/or pedicled flaps. In total, 12 patients underwent phalloplasty with urethral lengthening, and 13 patients without urethral lengthening. An overview of patient demographics is provided in Table 1. Four patients had a history of smoking, there were no active smokers. There was 1 patient with comorbid, noninsulin-dependent, diabetes. One patient had hypertension, which was controlled with oral anti-hypertensive medication.

**Table 1.** Patient demographics

	Total (n = 25)	Center 1 (n = 10)	Center 2 (n = 12)	Center 3 (n = 3)
Phalloplasty type, n				
FRFF	10	4	5	1
ALT	6	-	5	1
SCIP	2	1	1	-
Groin	1	-	-	1
Combination flaps	6	5	1	-
With urethral lengthening, n				
Yes	12	9	3	-
No	13	1	9	3
Mean age at prosthesis implantation $\pm$ SD	36 $\pm$ 9	41 $\pm$ 7	34 $\pm$ 8	29 $\pm$ 9
Mean BMI, kg/m <sup>2</sup> $\pm$ SD	24.6 $\pm$ 3.2	23.5 $\pm$ 4.0	25.4 $\pm$ 2.3	25.3 $\pm$ 1.7
Time after phalloplasty, years $\pm$ SD	3.6 $\pm$ 2.5	3.7 $\pm$ 2.2	3.4 $\pm$ 2.5	4.0 $\pm$ 3.0

ALT = anterolateral thigh; BMI = body mass index; FRFF = free radial forearm flap; SCIP = superficial circumflex iliac artery perforator flap.

### Surgical Outcomes

An overview of individual results is presented in Table 2. Immediate (Figure 2) and 3-month postoperative examples (Figure 3) are provided. Of 25 included patients, 11 (44%) had a Clavien-Dindo grade IIIa postoperative complication. There were no Clavien-Dindo grade IV or V complications. With a mean follow-up of 6.3 months, prosthesis explantation was performed in 11 patients. Explantation was performed because of because of infection (n=3), protrusion (n = 4, for an example, see Figure 4) or pubic pain (n = 1). In 3 patients, the prosthesis was explanted because the permanent rigid phallus caused limitations in their social activities (eg, during fitness). Of those with the prosthesis in place, 13 of 14 (93%) were able to engage in penetrative sexual intercourse. In the 1 patient who was not able to engage in penetrative sexual intercourse, this was because the phallus was too short.

**Table 2.** Individual Patient Surgical outcomes after implantation of the ZSI 100 FtM Malleable Penile Implant

Pa-tient ID	Surgical center	Phallo-plasty	Urethral lengthening	Age at im-plantation	Time af-ter phal-loplasty (years)	BMI (kg/m <sup>2</sup> )	Prosthe-sis	Postoperative compli-cations	Clinical follow-up (months )	Penetrative sexual in-tercourse possible?
1	Center 1	FRFF	Yes	27	3.9	26	ZSI 100 FTM	-	4.0	No
2	Center 1	FRFF	Yes	45	4.3	31	ZSI 100 FTM	+3m explantation be-cause of protrusion	6.5	-
3	Center 1	ALT+FRFF	Yes	33	4.5	18	ZSI 100 FTM D13	+5m explantation, be-cause of difficulty liv-ing with the current prosthesis, as it is visi-ble in his pants. Pros-thesis replaced with ZSI 475 FtM inflatable prosthesis.	5.5	-
4	Center 1	FRFF	Yes	50	1.8	26	ZSI 100 FTM	-	5.6	Yes
5	Center 1	SCIP+SCIP	Yes	54	1.5	25	ZSI 100 FTM	-	4.1	Yes
6	Center 1	ALT+FRFF	Yes	37	7.3	27	ZSI 100 FTM	+3m explantation, be-cause of difficulty liv-ing with the current prosthesis, as it is visi-ble in his pants. Pros-thesis replaced with ZSI 475 FtM inflatable prosthesis.	3.7	-
7	Center 1	ALT+FRFF	Yes	40	2.6	20	ZSI 100 FTM	-	2.9	Yes, Nosex-ual partner

8	Center 1	SCIP+SCIP	Yes	43	1.6	19	ZSI 100 FTM D13	-	3.1	Yes
9	Center 1	FRFF	Yes	41	7.9	23	ZSI 100 FTM	-	2.6	Yes
10	Center 1	SCIP	No	37	1.5	20	ZSI 100 FTM	-	2.1	Yes
11	Center 2	ALT	no	28	1.0	27	ZSI100 FTM	+2wk explantation because of protrusion	2.9	-
12	Center 2	ALT	no	43	1.2	26	ZSI100 FTM	+2 wk Explantation because of infection	16.6	-
13	Center 2	ALT	no	22	1.8	24	ZSI100 FTM	-	15.0	Yes
14	Center 2	ALT	no	26	3.3	25	ZSI100 FTM	-	18.2	Yes
15	Center 2	FRFF	yes	48	5.3	29	ZSI100 FTM	-	10.1	Yes
16	Center 2	ALT	no	37	1.1	30	ZSI100 FTM	+2m explantation because of protrusion	1.6	-
17	Center 2	FRFF	yes	42	8.2	26	ZSI100 FTM	+4m explantation because of protrusion	17.0	-
18	Center 2	ALT+FRFF	yes	46	6.9	22	ZSI100 FTM	-	8.3	Yes
19	Center 2	SCIP	no	25	6.5	24	ZSI100 FTM	+4m explantation because of infection	4.1	-
20	Center 2	FRFF	no	33	2.4	24	ZSI100 FTM	Explantation because of pubic pain	1.0	-
21	Center 2	FRRF	no	32	1.2	23	ZSI100 FTM	+1m explantation because of infection	1.2	-
22	Center 2	FRFF	no	31	1.9	25	ZSI 100 FTM D13		1.0	Yes
23	Center 3	FRFF	no	27	2.2	26	ZSI100 FTM	+6m explantation because of difficulty living with the prosthesis	6.1	-
24	Center 3	ALT	no	20	1.5	27	ZSI100 FTM	-	7.8	Yes
25	Center 3	Groin flap	no	42	8.2	23	ZSI100 FTM	-	5.5	Yes

## DISCUSSION

In this article, the surgical outcomes of implantation of the ZSI 100 FtM Malleable Penile Implant were described in 25 transgender men after phalloplasty. With a mean follow-up of 6.3 months, prosthesis explantation because of complications was performed in 8 patients (32%). The main causes were infection (n = 3), protrusion (n = 4), or pubic pain (n = 1). In an additional 3 patients, the prosthesis was explanted because the permanent rigid phallus caused limitations in their social activities (eg, during fitness).

Current literature on penile prostheses in transgender men has focused predominantly on prostheses designed for cisgender men. There are 4 major studies on this subject, all of retrospective nature, that report use of a wide range of prostheses and revision rates varying from 29-47%.<sup>4-6,8</sup> In which way this data is usable in the general population of transgender men is debatable, because of the retrospective nature of these studies and high surgeon, center, and prosthesis variability. When focusing on prostheses specifically designed for transgender men, only 1 study is published on this subject. Neuville et al<sup>7</sup> reported 20 transgender men who underwent implantation of the 3-piece inflatable ZSI 475 FtM between June 2016 and September 2017 in a single-surgeon retrospective case series. With a mean follow-up of  $8.9 \pm 4.0$  months, the overall revision rate was 19%, due to infection (n = 1), mechanical failure (n = 2) or malpositioning (n = 1).

Although the infection rate in our study, 12%, is comparable to published literature, explantation because of prosthesis protrusion occurred frequently (16%). In our experience, protrusion may occur when the prosthesis is cut too long, which may result in pressure ulceration at the top of the neophallus. Cutting it too small will lead to a droopy distal part of the penis with subsequent problems to engage in penetrative sexual intercourse. The relatively high rate of protrusion was observed predominantly in the beginning of the learning curve. With increased experience, and improved implant design, we expect the protrusion rate to drop. After the first few patients, the postoperative protocol was changed. Patients are now advised to wear the neophallus cranially, as to diminish internal pressure from the prosthesis on the neophallic top.

The design of the prosthesis has changed over time. Initially, the prosthesis had a longer internal wire; however, this was shortened, because a few cases (elsewhere) were described with breaking of the wire. Our experience is that the short wire provides poor malleability in these prostheses, and changes were made to make the wire longer again.

In our experience with the ZSI 100 Malleable Penile Implant, we noticed several practical advantages and disadvantages, which are listed below.

#### Advantages

- It is easy to implant, without major surgery and morbidity.
- There is a choice in prosthesis width.
- The prosthesis can be individually cut to size, based on individual penile dimensions.
- The fixation plate is adequate for multiple-point fixation.
- It is easy to use for patients.
- Material fatigue is not likely to occur in malleable prostheses.
- In patients with the prosthesis in place, postoperative rigidity is good and patients are generally able to engage in penetrative sexual intercourse.

#### Disadvantages

- A total flaccid penile state does not exist with a malleable prosthesis, which takes getting used to. Some patients underwent prosthesis explantation because of this discomfort.
- In case of a short neophallus, the wearability in everyday life is limited, due to the fact that there is limitation on bending of the implant.

Changes to the implant design in the future

may, however, eliminate this disadvantage.

- The fixation plate is quite large and is anchored to the sensate pubic periosteum. Some patients experience pubic pain or notice existence of the plate.

- A learning curve exists, for example, for cutting the prosthesis

to adequate size and correct placement onto the pubic bone. Cutting it too long will possibly lead to skin erosion and subsequent explantation.

Cutting it too small will lead to a droopy distal part of the penis with subsequent problems to engage in penetrative sexual intercourse.

Transgender men need to be counseled before prosthesis implantation on specific (dis)advantages of the implant. During counseling, patient preference, phallic dimensions, social activities, and clothing have to be taken into account before choosing a malleable prosthesis, such as the ZSI 100 FtM Malleable Penile Implant.

Strengths of this study comprise the completeness of data and that it reports on the use of a new device in the population of transgender men after phalloplasty. It also provides information on the use of malleable prostheses, whereas current literature predominantly focusses on hydraulic devices. This is a multi-center setting with the same peri-operative protocol. Weaknesses comprise the retrospective nature of the study, short follow-up time, and relatively small number of patients. No information on flap sensibility was present, whereas the absence of this could be an important risk factor in patients with prosthesis protrusion. Patient-reported outcome measures were not reported in this study. Data on neophallic length and prosthesis length was not available for all patients, which could be of importance as a factor leading to protrusion.

## CONCLUSION

Complication rates of the malleable ZSI implantation seem high at the start of the learning curve. Although designed specifically for the transgender community, not all transgender patients will be eligible for this type of prosthesis. Patients need to be well counseled on specific pros and cons of the prosthesis.

Patients need to be aware that a total flaccid penile state does not exist after malleable prosthesis implantation, which can influence social activities. Improvements are being made on the implant design.

**Table 2.** Individual outcomes after implantation of the ZSI 100 FtM Malleable Penile Implant

Patient ID	Surgical center	Phalloplasty	Urethral lengthening?	Age at implantation	Time after phalloplasty (years)	BMI (kg/m <sup>2</sup> )	Prosthesis	Postoperative complications	Clinical follow-up (months)	Penetrative sexual intercourse possible?
1	Center 1	FRFF	Yes	27	3.9	26	ZSI 100 FTM	-	4.0	No
2	Center 1	FRFF	Yes	45	4.3	31	ZSI 100 FTM	+3 mo explantation because of protrusion	6.5	-
3	Center 1	ALT + FRFF	Yes	33	4.5	18	ZSI 100 FTM D13	+5 mo explantation, because of difficulty living with the current prosthesis, as it is visible in his pants. Prosthesis replaced with ZSI 475 FtM inflatable prosthesis.	5.5	-
4	Center 1	FRFF	Yes	50	1.8	26	ZSI 100 FTM	-	5.6	Yes
5	Center 1	SCIP + SCIP	Yes	54	1.5	25	ZSI 100 FTM	-	4.1	Yes
6	Center 1	ALT + FRFF	Yes	37	7.3	27	ZSI 100 FTM	+3 mo explantation, because of difficulty living with the current prosthesis, as it is visible in his pants. Prosthesis replaced with ZSI 475 FtM inflatable prosthesis.	3.7	-
7	Center 1	ALT + FRFF	Yes	40	2.6	20	ZSI 100 FTM	-	2.9	Yes, but no sexual partner
8	Center 1	SCIP + SCIP	Yes	43	1.6	19	ZSI 100 FTM D13	-	3.1	Yes
9	Center 1	FRFF	Yes	41	7.9	23	ZSI 100 FTM	-	2.6	Yes
10	Center 1	SCIP	No	37	1.5	20	ZSI 100 FTM	-	2.1	Yes
11	Center 2	ALT	No	28	1.0	27	ZSI100 FTM	+2 wk explantation because of protrusion	2.9	-
12	Center 2	ALT	No	43	1.2	26	ZSI100 FTM	+2 wk explantation because of infection	16.6	-
13	Center 2	ALT	No	22	1.8	24	ZSI100 FTM	-	15.0	Yes
14	Center 2	ALT	No	26	3.3	25	ZSI100 FTM	-	18.2	Yes
15	Center 2	FRFF	Yes	48	5.3	29	ZSI100 FTM	-	10.1	Yes
16	Center 2	ALT	No	37	1.1	30	ZSI100 FTM	+2 mo explantation because of protrusion	1.6	-
17	Center 2	FRFF	Yes	42	8.2	26	ZSI100 FTM	+4 mo explantation because of protrusion	17.0	-
18	Center 2	ALT + FRFF	Yes	46	6.9	22	ZSI100 FTM	-	8.3	Yes
19	Center 2	SCIP	No	25	6.5	24	ZSI100 FTM	+4 mo explantation because of infection	4.1	-
20	Center 2	FRFF	No	33	2.4	24	ZSI100 FTM	Explantation because of pubic pain	1.0	-
21	Center 2	FRFF	No	32	1.2	23	ZSI100 FTM	+1 mo explantation because of infection	1.2	-
22	Center 2	FRFF	No	31	1.9	25	ZSI 100 FTM D13	-	1.0	Yes
23	Center 3	FRFF	No	27	2.2	26	ZSI100 FTM	+6 mo explantation because of difficulty living with the prosthesis	6.1	-
24	Center 3	ALT	No	20	1.5	27	ZSI100 FTM	-	7.8	Yes
25	Center 3	Groin flap	No	42	8.2	23	ZSI100 FTM	-	5.5	Yes

ALT = anterolateral thigh flap; BMI = body mass index; FRFF = free radial forearm flap; SCIP = superficial circumflex iliac artery perforator flap.



Figure 2. Immediate postoperative result after anterolateral thigh flap (left) and superficial circumflex iliac artery perforator flap phalloplasty (right).





Figure 3. Result 3 months after superficial circumflex iliac artery perforator flap phalloplasty with superficial circumflex iliac artery perforator flap neo-urethra. Figure 3 is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org)



Figure 4. Example of prosthesis extrusion. Figure 4 is available in color online at [www.jsm.jsexmed.org](http://www.jsm.jsexmed.org)

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### **Part three**

#### **Shared decision making and patient reported outcomes after gGAS**

## Chapter 8

### Development of a Decision Aid for Genital Gender-Affirming Surgery in Transmen

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#### ABSTRACT

**Background:** As genital gender-affirming surgery (GAS) is a demanding and life-changing intervention, transmen should be able to make choices about the surgical treatment based on outcomes that are most important to them, while taking into consideration the concomitant risks involved.

**Aim:** Develop a decision aid (DA) for genital surgery in transmen (DA-GST) that can assist both transmen and health care professionals (HCPs) in making a well-informed decision about the surgical treatment.

**Methods:** A qualitative focus group study was performed. 5 Focus groups were organized with both HCPs and transmen. These were led by an independent professional moderator. Data collected during these focus groups were analyzed to provide content for the DA.

**Outcomes:** To develop content for a DA-GST.

**Results:** Data collected during the focus groups related to the treatment options, information deemed relevant by transmen, and the arguments for or against each treatment option. Collected items were divided into the following themes: outcome, quality of life, environment, sexuality, and beliefs.

**Clinical Implications:** The tool will be useful in assisting both transmen and HCPs in the shared decision-making process regarding genital GAS by exploring which domains are most relevant for each specific individual.

**Strengths & Limitations:** This DA was developed according to an iterative participatory design approach to fit the needs of both transmen and HCPs. Issues that transmen find important and relevant pertaining to genital GAS were translated into arguments that were incorporated in the DA-GST. The study is limited by the group that had participated. Not all arguments for or against specific surgical options may be covered by the DA-GST.

**Conclusion:** An online DA was developed to support transmen with their decision-making process concerning all surgical options for removal of reproductive organs and genital GAS.

#### INTRODUCTION

Gender dysphoria refers to the distress resulting from a marked incongruence between the assigned gender and experienced gender. In Western society, a rapidly growing number of people with gender dysphoria seeks treatment. Also, at the Center of Expertise on Gender Dysphoria in the VU University Medical Center, the number of new applications has grown exponentially over the last 10 years (Figure 1). The reason for this rise is unknown. Possibly this is partly due to increased exposure and acceptance of gender variance in society.

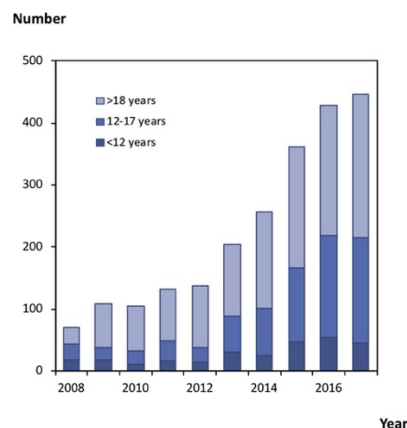


Figure 1 The number of transmen seeking treatment for gender dysphoria who registered as a new patient in our clinic over recent years.

The now generally accepted treatment of gender dysphoria aims to align the physique of a person to their experienced gender identity. This gender-affirming treatment comprises a combination of psychological counseling, hormonal therapy and, if desired, genital gender-affirming surgery (GAS). Historically, GAS includes the removal of the native reproductive organs and parts of the native genitals, and the creation of genitals of the desired gender, while retaining a good urologic and sexual function.

In recent years, views on the concepts “gender” and “gender identity” have been changing. While these used to be binary concepts (either female or male), today, gender is viewed more as a fluid spectrum, where someone may have a more or less feminine or masculine expression. Similarly, people may identify in different degrees with a male or female identity, or even outside of this spectrum. This changing paradigm has also influenced our approach toward the treatment of gender dysphoria, which is reflected by an increased attention to individualized treatment and partial treatment requests.<sup>1</sup> With regard to GAS, this paradigm shift leads to a more individualized treatment, in which partial treatment requests can also be discussed. This requires an improved understanding of the individuals’ wishes and expectations, but it also requires a surgeons’ conscientious and judicious search for, and offering of, various treatment options.

Multiple options exist for GAS in transmen. The various choices comprise combinations of removal of native reproductive organs and part of the native genitals, and various options for the creation of a masculine genital with or without urethral lengthening. These various choices yield different physical requirements (eg, body mass index and required donor tissue) and expected outcomes. These various choices also have different risks of complications.<sup>2-12</sup>

The choice between the many different options for GAS mainly depends on: (1) feasibility: the possibility to perform the technique (including the surgeons’ armamentarium and requirements of the patient’s physical condition); (2) wishes and expectations: with regard to cosmetic outcome, sexual and urological function, and fertility; and (3) risk and coping: the burden of the surgery including donor site morbidity and the risk of complications relative to coping capacity. Weighing all of these matters to come to a good decision is challenging for both transman and surgeon.

Presently, in our Center of Expertise on Gender Dysphoria, the choice for a certain GAS is made after receiving extensive information about the surgical options, consultation with a gender psychologist and hereafter consultation with the plastic surgeon and the urologist. However, satisfaction after the surgery varies, and it appears that a mismatch between expectations and realization exists in some individuals.<sup>13</sup> This mismatch could potentially lead to dissatisfaction and preventable re-operations, causing additional cost, burden, and potentially more donor-site morbidity and complications.

As GAS is a demanding and life-changing event, the transman should be able to make choices about the surgical treatment based on outcomes that are most important to him, while taking into consideration the (donor-site) scars and possible complications involved. For this reason, a tool that can assist both transman and health care professional (HCP) in making a well-informed decision about the treatment is particularly necessary.

Multiple studies in other treatment areas showed that decision aids (DAs) improve patients’ knowledge and participation in decision-making, help patients to have more accurate expectations of possible benefits and harms of treatments, and support patients to reach choices that are more consistent with their informed values.<sup>14-18</sup> From a health care provider’s perspective, it helps to reach a common understanding of the risks and benefits associated with treatment choices and tailor treatment choices to each patient’s circumstance.<sup>19</sup>

#### Aims

We aim to develop a DA for genital surgery in transmen (DA-GST). The purpose of the DA-GST is to facilitate transmen’s participation and to support them in making thoughtful choices among treatment options by providing information on the options and outcomes relevant to the person.<sup>19</sup> This DA-GST

serve as a valuable tool to assist in shared decision-making (SDM) between the HCPs and the transman.

## METHODS

A qualitative focus group study was performed. Focus groups with HCPs and transmen were selected as the best method to collect information. In total, we organized 5 focus groups with both transmen and HCPs. Each focus group took between 3e4 hours. Participants were transmen (n 1/4 12) who already underwent genital surgery, transmen who were considering undergoing surgery or who decided not (yet) to undergo genital surgery. Furthermore, HCPs (n 1/4 9) involved in treatment of individuals with gender dysphoria (plastic surgeons, gynecologists, urologists, physician assistants, and psychologists) participated in the focus groups. The composition of the focus groups varied, but in all groups both transmen and HCPs were represented. Transmen were recruited via the transgender support group in The Netherlands and through their plastic surgeon. All HCPs involved were working at the Center of Expertise on Gender Dysphoria of the VU University Medical Center, Amsterdam, The Netherlands.

All focus groups were led by an independent professional moderator. The approach was to let all participants write down their “answers or issues” on a specific topic first, before letting everyone in turn share this in the group. This procedure prevented that some people in the group may be overshadowed, and it stimulated active participation of all group members. The suggestions were then translated into common Dutch language. The procedure was repeated until no new information could be collected.

The full process of DA development is illustrated in Figure 2. First, the scope of the DA-GST was charted. The first focus group was used to extensively map all possible issues and topics that should be covered. Data collected during this meeting were analyzed through thematic analysis in which subjects should be addressed were categorized into themes by the participants of the focus groups. This provided a so-called “map” for the DA, but without content. The next 2 focus groups were used to collect arguments for or against all possible treatment options with regard to the subjects/themes that were previously established as being important. Some adaptations of the structure and themes (ie, the map) were also discussed. Data collected during these focus groups were analyzed literally to provide content for the DA. Arguments for and against each procedure were established and clustered within the selected themes; these themes were then subdivided into specific subjects to cluster the arguments. Based on this subdivision, a first article design of the DA-GST was drafted. The last 2 focus groups were used to test the concept version of the DA-GST, with respect to content, comprehensiveness, clarity, language, and accuracy. Hereafter, the digital DA-GST was developed. After a testing period, where both patients and HCPs assessed the tool, final adaptations were made and the digital DA-GST was finalized.

## RESULTS

### Scope of the DA-GST

According to all attendants, the DA-GST should be designed to help transmen to think about what is most important for them as an individual when deciding for or against undergoing 1 or more surgical procedures. The DA-GST should not render 1 “best choice.” Its purpose is to facilitate participation in the SDM process and to support transmen in making specific and deliberative choices among treatment options. The information should encompass a broad spectrum of motives and possibilities for genital GAS. Within the group of HCPs and transmen it was agreed that the content of the DA-GST should focus primarily on desired outcomes and realistic expectations, and it should not aim to provide extensive medical information about the individual surgical procedures.

### DA-GST Design

Taking the above into account, subjects and questions (items) that should be addressed in the DA were exhaustively collected during the first focus group. All items were noted during the meeting and categorized afterward. The items collected during the first focus groups were grouped into the following main themes: outcome, quality of life, environment, sexuality, and beliefs.

It was agreed by all focus group attendants that the DA-GST structure would be the clearest if it followed the multiple surgical options for GAS in transmen. During the second focus group all (combinations of) surgical options for removal of the native internal and external female genitals, and/or the construction of a masculine genital were established by the HCPs. The surgical options were categorized by gynecological procedures and (plastic-urological) reconstructive treatments provided in our clinic. The gynecological procedures included 5 options: (1) total laparoscopic hysterectomy and bilateral salpingo-ovariectomy (BSO) combined with top surgery, (2) robotic colpectomy and hysterectomy with/without BSO, (3) total laparoscopic hysterectomy only, (4) BSO only, and (5) colpectomy only. Reconstructive procedures included metoidioplasty and phalloplasty with scrotoplasty, both with or without urethroplasty. For all procedures, a short description was given to clarify what the procedure entailed. In addition, the requirements for undergoing a specific procedure were listed as well. Information collected in the first 2 focus groups rendered a map for the DA-GST (Figure 3).

### DA-GST Content

Focus groups 3 and 4 were used to comprehensively collect arguments for and against each procedure. All items, which were collected during the first focus group were addressed, taking the defined main themes into consideration. Also, new items were put forward.

With regard to information about the procedures, it was decided to provide general information only. The treating HCPs should inform the patient about the details of the procedure, as these may change over time and depend on the individual situation. For instance, surgical reconstructive techniques of metoidioplasty and phalloplasty are evolving rapidly at this moment. Both procedures require tissue transfer from a donor site, but

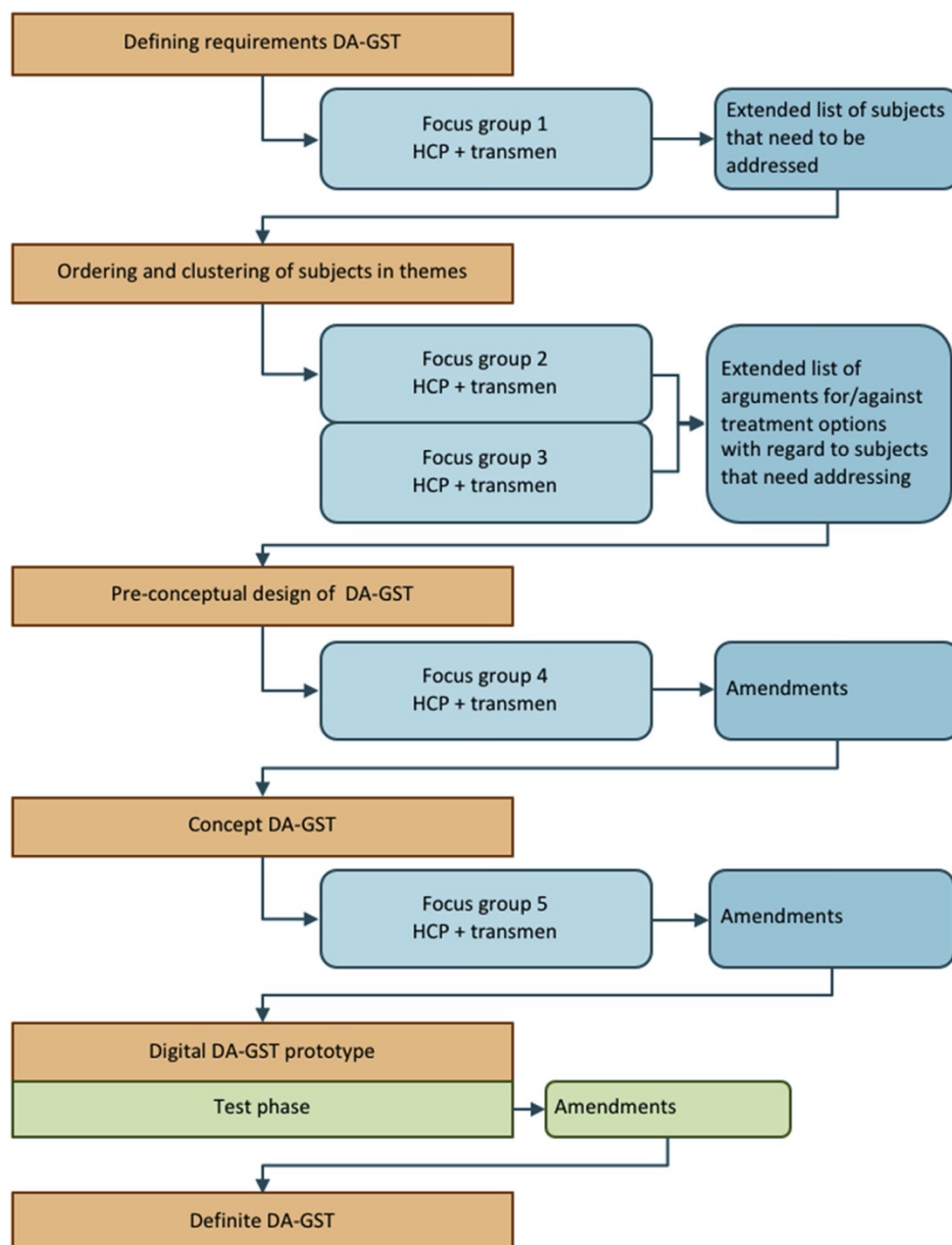


Figure 2. A structured iterative process is used to develop the decision aid for genital gender-affirming surgery in transmen (DA-GST). Focus groups are held to collect qualitative data. Subsequently, these data are analyzed and processed to proceed to the next step in the development. HCP 1/4 health care professional.

specific donor site locations may vary. Quantitative information on outcomes will also not be included in the DA-GST, because reliable evidence on clinical outcomes of GAS in transmen is currently insufficient. Instead, relative risks of complications are included, for instance, more problems with micturition are expected in phalloplasty with urethral lengthening compared with phalloplasty without urethral lengthening.

#### Completion of the DA-GST

Much effort was put into appropriate phrasing. Although not all individuals who opt for masculinizing genital GAS may identify as a “transman,” it was decided by the transmen participants (after deliberation with peers) that this was still the most appropriate term to use for the target population. It was also difficult to find appropriate common nomenclature for “metoidioplasty” and “phalloplasty,” without giving an inherent value judgment. The medical term “micropenis” (ie, a penis size smaller than 2.5 SD from the mean in a population) was dismissed by transmen. Instead we used “creation of a small penis” (metoidioplasty) and “creation of a large penis” (phalloplasty).

In order to facilitate implementation in decision-making and clinical practice, the digital DA-GST was developed in an online format compatible with desktops, tablets, and handhelds as well as for several smartphone platforms (Figure 4). Both HCPs and transmen checked the final DA-GST for inaccuracies and here- after the DA was finalized.

## Decision Aid for Surgery in Transmen

What are options for genital surgeries in trans men?

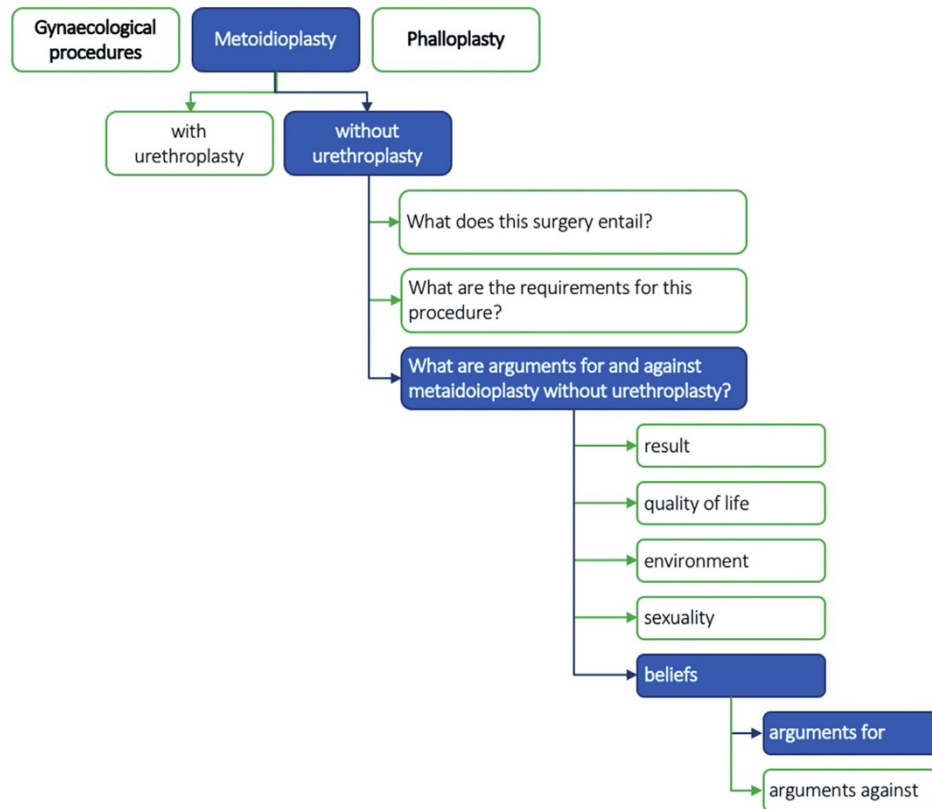


Figure 3. A map of the decision aid for genital gender-affirming surgery in transmen was made in which the structure of the tool and the content for all surgical procedures was written. In blue, an example of the structure for one of the surgical procedures (metoidioplasty without urethral lengthening) is given. The same structure applies to all other surgical procedures.

## DISCUSSION

The aim of this study was to create a DA for transmen and HCPs to assist in the decision-making process for individuals considering genital GAS, the DA-GST. Transmen may opt for this surgery as part of their treatment to resolve the incongruence between their gender identity and their assigned gender. This DA-GST was created together with transmen, specifically aiming to integrate experiences of transmen into the decision-making

process.<sup>21</sup> Issues that transmen find important and relevant pertaining to genital GAS were translated into arguments that were incorporated in the DA-GST.

Over the past years, several developments have instigated a change in the treatment approach of individuals experiencing gender dysphoria, resulting in more individualized health care. Societal changes include legal changes as well as changes in general perceptions of gender (and transgender individuals). For the Dutch situation specifically, it has been possible to change sex registration on one's birth certificate since 1985. However, the person was required to have undergone GAS and had to be made infertile. This legal requirement "naturally" resulted in uniform treatment requests in transmen (ie, removal of reproductive organs with/without the surgical creation of a penis). In 2014, following the European trend, the Dutch government adopted an updated version of this law<sup>22</sup>, permitting people aged 16 years or above to change their legal sex without any treatment requirements and court procedures. As a result, genital GAS treatment requests—although not declining in number—are now primarily initiated by people's intrinsic motives. However, the content of treatment requests has changed and the demand for partial treatments has grown as well.

Another factor contributing to changing treatment requests includes the evolving societal perspective on gender. The concept "gender" is shifting from a binary, ie, man or woman, toward a much broader concept in which gender is seen as a spectrum. New terms were introduced such as "gender fluidity," "gender variance," and "gender neutral." In line with this, transgender individuals express more variance in how they experience and express their gender identity. Consequently, treatment requests are varying also. Individuals may not necessarily experience dysphoria with certain body parts and/or do not need certain surgeries to affirm their identity. This translates into partial treatment gaining popularity during all phases of treatment.<sup>13</sup>



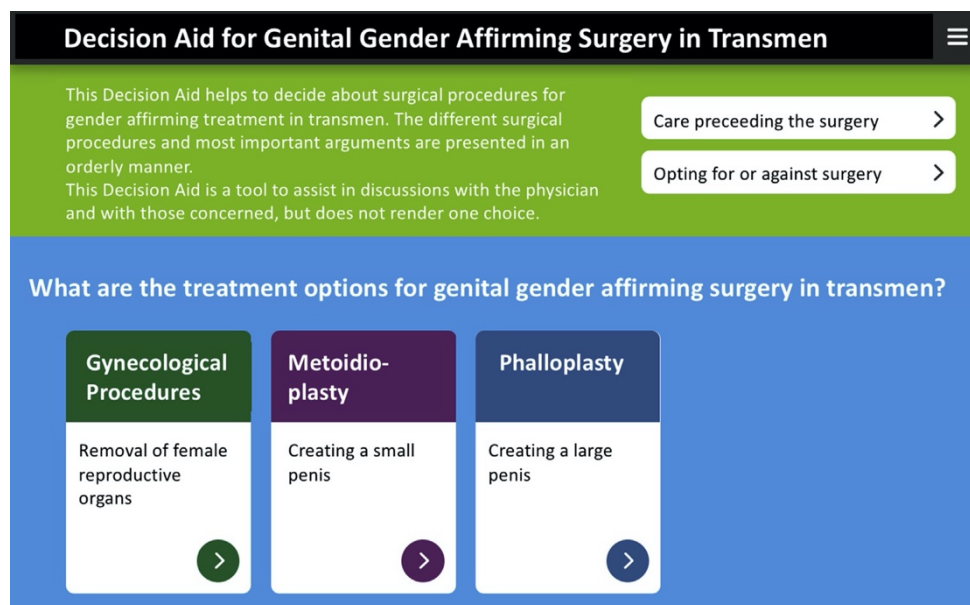


Figure 4. Decision aid for genital gender-affirming surgery in transmen. Home page of the online tool is shown.

At the same time, transgender medicine evolves within a larger paradigm shift in health care: a system in which patients are more centered and decisions are deliberately taken with shared responsibility. In case of transgender health care, this development changes both the role of the health care provider and of the transgender individual. While HCPs offer treatment options to those applying for care, transgender individuals take a more active role within clinical contacts when developing and voicing their preferences. This ultimately leads to more autonomy during clinical encounters and ownership over one's treatment (outcomes).<sup>23</sup>

In order to facilitate the process toward choosing the treatment policy that is best suited for the individual, SDM is often applied. SDM includes the notion of a medical encounter as a "meeting of experts"—the physician as an expert in medicine and the patient as expert in his or her own life.<sup>24</sup> However, for such a "meeting of experts" to become effective, it is important that the physician obtains the relevant information about what the patients finds important in his/her life, while the patient needs to be informed about the relevant aspects of different treatment options. And subsequently, these 2 areas of information should be consolidated toward the available treatment options. The currently developed DA-GST is a tool that provides information based on experiences of transmen to assist in the SDM process with regard to genital GAS.<sup>25</sup>

Returning to the criteria of feasibility, desirability, and risk and coping ability, as mentioned in the "Introduction" section, it is important for SDM to include all this relevant information. The method for developing the present DA-GST allowed for the inclusion of both surgically/medically relevant information, as well as information about the transman in a broader perspective. This resulted in the definition of 5 main themes to consider during decision-making: outcome, quality of life, environment, sexuality, and beliefs. While some subjects have been studied thoroughly, in relation to genital GAS (eg, clinical outcomes or quality of life), taking the patient-centered approach also addressed less frequently studied subjects such as one's environment, sexuality, and beliefs. By using the DA-GST, clinicians are reminded to address these topics as well, while those applying for care are supported in overseeing all the consequences regarding their choices to facilitate the best (surgical) option for them. This again may provide individuals with insights on why they choose a certain option, rather than "just" what surgery. For SDM to be relevant, it is crucial that various treatment options are offered explicitly. The DA-GST provides information about general treatment options but does not provide information about each specific surgical technique, hence, responsibility for providing this specific information still lies with the treating surgeon. It is important to realize that not all surgical options may be offered at a single center. The HCP should be aware of the full spectrum of surgical treatments and techniques and discuss all options with the patient. When necessary, the patient should be referred to a center where alternative surgical treatments are offered.

While this study was designed and conducted in cooperation with transmen themselves, the study may be limited by the group that had participated. As they were mostly transmen who were somehow involved in health care facilities or support groups, and were willing to participate, the input for the DA-GST may not fully cover all associated arguments. Therefore, such a DA should constantly develop and re-iterate. Future studies might focus on the clinical effectiveness of the DA (eg, feelings of autonomy and ownership, and post-operative satisfaction and quality of life). In addition, future research should focus on outcomes of GAS that transmen themselves find most important.

## CONCLUSION

The present study describes the development of a digital DA for genital GAS in transmen. This online tool gives insight into arguments for or against each surgical option from a transman's perspective. It is used to support SDM between the transman and the HCP.

## ACKNOWLEDGEMENT



We would like to give special thanks to the transmen who participated in the focus groups. We thank “De Argu- mentenfabriek” for their methodological contribution to the development of the DA.

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## Chapter 9

### A Longitudinal Study of Motivations Before and Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen

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#### ABSTRACT

**Background:** Genital dissatisfaction is an important reason for transmen to undergo genital gender-confirming surgery (GCS; phalloplasty or metoidioplasty). However, little is known about motives for choosing specific techniques, how transmen benefit postoperatively, and whether psychosexual outcomes improve.

**Aim:** To evaluate motivations for and psychosexual outcomes after GCS.

**Methods:** A longitudinal study of 21 transmen at least 1 year after GCS was conducted. Participants were recruited through their surgeon. Data were collected when they applied for surgery and at least 1 year after surgery.

**Outcomes:** Data collection included semistructured questionnaires on motivations for surgery, postoperative experiences, and standardized measures of psychological symptoms, body image, self-esteem, sexuality, and quality of life (pre- and postoperative). Information on surgical complications and corrections was retrieved from medical records.

**Results:** Most participants underwent phalloplasty with urethral lengthening using a radial forearm flap. Although problematic voiding symptoms were prevalent, many participants were satisfied with their penile function. The strongest motivations to pursue penile surgery were confirmation of one's identity (100%), enabling sexual intercourse (78%), and voiding while standing (74%). No significant differences between postoperative and reference values were observed for standardized measures. After surgery, transmen were more sexually active (masturbation and with a partner) and used their genitals more frequently during sex compared with before surgery (31e78%).

**Clinical Implications:** The present study provides input for preoperative decision making: (i) main motives for surgery include identity confirmation, voiding, and sexuality, (ii) surgery can result in more sexual activity and genital involvement during sex, although some distress can remain, but (iii) complications and voiding symptoms are prevalent.

**Strength and Limitations:** Study strengths include its longitudinal design and the novelty of the studied outcomes. The main limitations include the sample size and the nature of the assessment.

**Conclusion:** Counseling and decision making for GCS in transmen should be a highly personalized and interdisciplinary practice.

#### INTRODUCTION

Gender dysphoria refers to the phenomenon in which a person experiences psychological distress resulting from incongruence between the assigned and the experienced gender identity.<sup>1</sup> As a result, a subgroup might apply for medical care. Gender-confirming medical care is generally conducted in interdisciplinary facilities and includes psychological counseling, cross-sex hormone treatment, and gender-confirming surgeries (GCSs).<sup>2</sup>

Transmen are assigned female at birth but identify as male or masculine. Medical care for this group can include testosterone therapy, hysterectomy with bilateral salpingo-oophorectomy, subcutaneous mastectomy, and genital GCS. Because much of the gender dysphoria might be related to female genitals,<sup>3</sup> approximately 30% of transmen apply for GCS.<sup>4,5</sup> Some reasons not to obtain GCS are associated risks, absence of genital dysphoria, and/or non-binary gender identities.<sup>6</sup>

The most performed and studied techniques of GCS in transmen include phalloplasty (eg, with free radial forearm flap [FRFF] or anterolateral thigh flap [ALTF]) and metoidioplasty.<sup>2,7</sup> The benefits of FRFF phalloplasty include pliable donor tissue, reliable vascularization, good phallic sensation, and the opportunity to implant erection prostheses.<sup>2,8</sup> Disadvantages include the high risk of flap-related complications and mutilating donor-site scarring.<sup>2,9</sup> Compared with FRFF phalloplasty, the advantage of ALTF phalloplasty includes less visible donor-site scarring, although the flap usually does not allow for a neo-urethra.<sup>2,8</sup> In general, in metoidioplasty, the hypertrophic clitoris, a consequence of testosterone therapy, is released by dissecting the urethral plate and suspensory ligaments. In addition, urethral lengthening can be performed using labia minora flaps and scrotoplasty can be performed using labia majora flaps.<sup>10</sup> Advantages of this procedure include lower complication rates compared with phalloplasty and good phallic sensation, although penetration is less frequently possible.<sup>2,8</sup>

Several studies have been published on complication rates and functional outcomes (eg, esthetics, voiding, and sensation) after GCS.<sup>7,11</sup> Most reported complications after phalloplasty are urethral fistulas and strictures, (partial) flap loss, and donor-site complications.<sup>11</sup> Phalloplasty in transmen generally yields a masculine genital appearance and good phallic sensation and voiding while standing is frequently possible. However, problems with urinary function are observed after surgery, including postvoid dribbling, incontinence, and an over-active bladder.<sup>12,13</sup>

Penetrative sex is possible for approximately 20% of transmen who undergo FRFF phalloplasty, although the implantation of erection prosthesis has not been specified. Erectile implants can facilitate (vaginal or anal) sexual intercourse, although implant malposition and dysfunction are possible issues.<sup>14,15</sup>

Because the various available GCS techniques have their pros and cons, surgery should be preceded by extensive counseling. In the literature, it is stated that a surgical technique is best selected based on the “individual’s goals and expectations.”<sup>7</sup> However, to date, little is known about the motivations of transmen to pursue GCS at all and why certain techniques are preferred.<sup>16</sup> Clinical experience and the scarce literature<sup>17</sup> suggest that a masculine genital appearance, voiding while standing, enabling the wearing of tight shorts, and sexuality play a role in the decision making of transmen. Nevertheless, data on the extent to which surgery contributes to resolving these issues remain largely unknown.

What is known is that metoidioplasty and phalloplasty are followed by high satisfaction rates of 93% and 78% to 100%, respectively.<sup>11</sup> Overall improvements of quality of life, lowered gender dysphoria, and lowered psychological symptoms after gender-confirming treatments as a whole have been reported<sup>5,18,19</sup> although limited prospective data on the effects of genital GCS specifically on these parameters are available. For sexuality, participants report a satisfactory sex life after phalloplasty<sup>20-22</sup>, although testosterone treatment is a contributory factor.<sup>23</sup> Initiating sexual contacts and undressing in public spaces could remain problematic after phalloplasty.<sup>24</sup> Because these issues could be motives for transmen to pursue GCS, more knowledge on the motives and psychosexual experiences could improve preoperative counseling, surgical decision making, and ultimately postoperative outcomes.

## **AIMS**

In this study we longitudinally assessed the functional and experienced outcomes after GCS in transmen. Preoperative motives to obtain certain surgical techniques were compared with postoperative experiences. We expected surgery would significantly improve psychosexual well-being and experiences would be influenced by more variables (eg, having a partner) than surgery alone.

## **METHODS**

### **Procedure**

From October 2015 through March 2016, all transmen who applied for GCS from 2011 through 2015 and were at least 1 year postoperative were invited to participate (N = 34). After obtaining written informed consent, participants received a paper questionnaire and voiding surveys. Non-responders were reminded by phone. Study participation was voluntary and the study was approved by the local ethics committee. Surgical care was conducted according to the World Professional Association for Transgender Health standards of care.<sup>7</sup> Patients were considered eligible for surgery based on no smoking, a body mass index of 18 to 30 kg/m<sup>2</sup>, and adequate epilation of the urethral donor site(s). In addition, preoperative counseling was conducted by (obligatory) consultations with a psychologist-sexologist, a plastic surgeon, and a urologist. If required, additional procedures before GCS included colectomy and donor-site tissue expansion. The psychologist-sexologist standardly discussed expectations and support of the transman and performed standardized assessment of psychological topics such as body image, self-esteem, and quality of life (used as baseline measures in this study). The surgical techniques performed included phalloplasty (based on ALTF and FRFF) and metoidioplasty with or without urethroplasty. The postoperative regimen included 5 to 7 days of hospital observation, 6 weeks of abstinence from heavy physical activity, and outpatient clinic visits with the urologist and/or plastic surgeon at 3 weeks and 3, 6, and 12 months. Follow-up visits with the psychologist-sexologist were possible upon request.

### **Participants**

21 of 34 transmen (62%) participated in this study. Of the non-participants, 1 did not want to participate because of lack of time and 12 did not respond. No significant differences were observed between participants and non-participants for age, education level, and surgical technique. The average follow-up time after surgery was 31 months.

### **Outcome Measures**

#### **Background Data**

Information on age, education level, and current partnership status was collected from medical records and self-report measures.

#### **Surgical Data**

Data on surgical techniques (including secondary corrections) and complications were retrieved from medical records and scored on standardized sheets. Complications were subdivided into short term (<3 weeks) and long term (>3 weeks) and reported as urinary complications (fistula, stenosis, spraying, or infection), flap complications (dehiscence or necrosis), and donor-site complications (necrosis or edema).

#### **Functional Outcomes**

Data on voiding and penile function were collected at follow-up. Voiding measures included the International Prostate Symptom Score (IPSS)<sup>25</sup> and 24-hour voiding diary. The IPSS is a 7-item measure assessing storage and voiding complaints. Scores of 7 or lower indicate mild symptoms, scores of 8 or higher indicate moderate symptoms, and scores of 19 or higher indicate severe symptoms. Experienced functional outcomes were surveyed by assessing agreement with 2 self-constructed statements: “I am satisfied with my voiding and sexual function” (0 = strongly disagree to 4 = strongly agree). On the same scale, participants were asked to rate the statements, “I regret that I have undergone genital surgery” and “With the current experience, I would have chosen a different type of genital surgery.”

## Motivations

Preoperatively, transmen were surveyed on the preferred GCS technique and the importance of certain predefined motivations (eg, identity, voiding while standing, and penetration). At follow-up, participants were asked about the extent to which the surgery contributed to resolving the initial issue (1 1/4 strongly to 4 1/4 not at all). Participants also were asked to provide additional comments on their motivations and post-operative experiences.

## Psychosexual Outcomes and Quality of Life

Pre- and postoperative data on psychosexual outcomes and quality of life were collected using questionnaires:

Quality of life. Quality was assessed with the Satisfaction With Life Scale (SWLS), a 5-item measure in which a higher sum score implies greater satisfaction<sup>26</sup>; the Subjective Happiness Scale (SHS), a 4-item measure in which a higher mean score corresponds with greater happiness<sup>27</sup>; and the Cantril Ladder (CL), in which people graded their lives on a scale from 0 (extremely bad) to 10 (excellent).<sup>28</sup>

Sexuality. In cooperation with psychologist-sexologists, a measure was constructed covering (changes in) sexual activity (eg, “Did your sexual partner touch your genitals during sexual activity during the past 3 months?” [never, sometimes, often, or very often]), relationships and orientation (modified Kinsey scale), and overall satisfaction (“completely agree” to “completely disagree”). Also, participants were asked to comment on their current sexuality and the impact of genital GCS (free text).

Body image and self-esteem. Body satisfaction was assessed using the Body Image Scale, with higher mean scores for the 6 subscales indicating greater dissatisfaction.<sup>3,29</sup>

Higher sum scores on the Rosenberg Self-Esteem Scale indicate higher self-esteem.<sup>30</sup>

Feelings of masculinity and femininity. Participants were asked to rate feelings about themselves on a self-constructed scale from 1 (fully male) to 10 (fully female).

Psychological symptoms. The Hospital Anxiety and Depression Scale was used to assess levels of anxiety and depression,<sup>31</sup> and subscale sum scores higher than 8 indicated clinical levels.

## Statistical Analyses

Background and surgical characteristics were presented as frequencies and means. Surgical motives and postoperative experiences were calculated as frequencies. Questionnaire outcomes were analyzed according to published manuals. Reference values were retrieved from the literature. Pre- and postoperative data were normally distributed; therefore, mean comparisons were performed using repeated measures and Student and 1-sample t-tests. Bonferroni correction was applied to correct for multiple testing. All analyses were performed in SPSS 22.0 (IBM Corp, Armonk, NY, USA).

## RESULTS

Characteristics of the participating sample are presented in Table 1. GCS was preceded by an average of 11 years of testosterone therapy and in most cases by chest surgery. For many, the period of testosterone therapy and counseling was relatively long because of long waiting lists for surgery.

**Table 1.** Study sample characteristics (N 1/4 21)\*

Postoperative follow-up (mo), mean (SD; minemax) <sup>†</sup>	31.4 (20.2; 13-99)
Age (y), mean (SD) <sup>†</sup>	40.1 (9.9)
Education level, n (%) <sup>‡</sup>	
None or elementary school	3 (14.3)
High school or vocational school	5 (23.8)
College or university	4 (19.0)
(Sexual) partner status, n (%) <sup>†</sup>	
Female partner	
Male partner	12 (63.2)
Single, no (sexual) partner	2 (10.5)
	5 (26.3)

**Table 2.** Surgical complications and additional procedures\*

	Phalloplasty (n=15)	Metoidioplasty (n=6)
Complications		
Long-term urinary complications		
Strictures	12 (80.0)	(33.3)
Fistula	5 (33.3)	0
Recurring UTI	4 (26.7)	0
Spraying	2 (13.3)	0
Flap complications	9 (60)	
Dehiscence	5 (33.3)	5 (83.3) <sup>†</sup>
Partial necrosis		1 (16.7)
Donor site complications		
Partial necrosis	4 (26.7)	—
Edema	2 (13.3)	—
Other (pain)	1 (6.7)	—
Additional procedures		
Testicle implants	10 (47.6)	
Erection prosthesis	0	
Glans plasty	3 (14.3)	
Scrotoplasty	3 (14.3)	

UTI=urinary tract infection.

\*Data are presented as number (percentage). Because of missing data and round-offs, percentages might not sum up to 100%.

<sup>†</sup> 1 scrotal dehiscence at follow-up.

BMI (kg/m<sup>2</sup>), mean (SD)<sup>‡</sup> 25.6 (4.2)

Previous surgery, n (%)<sup>†</sup>

Subcutaneous mastectomy  
Hystero-oophorectomy 21 (100.0)  
Colpectomy 21 (100.0)  
16 (76.2)

Phalloplasty

FRFF 8 (38.1)  
FRFF + ALTf 5 (23.8)  
ALTf 2 (9.5)

Metoidioplasty

With urethral lengthening 2 (9.5)  
Without urethral lengthening 4 (19.0)

ALTf = anterolateral thigh flap; BMI = body mass index; FRFF = free radial forearm flap;  
max = maximum; min = minimum.

\*Because of missing data and round-offs, percentages might not sum up to 100%.

<sup>†</sup> Follow-up data.

<sup>‡</sup> Baseline data.

#### Surgical Details

The most performed surgical technique was phalloplasty with urethral lengthening (mostly by FRFF). Strictures of the urethra occurred in 80% of this group, and often multiple stenoses occurred in 1 patient (up to 4 times; Table 2). All strictures occurred in the group with urethral lengthening (odds ratio = 2.67, 95% CI = 1.09-6.54, P = .003).

## Functional Outcomes

IPSS sum scores did not differ significantly between the phalloplasty (mean = 11.3, SD = 8.3) and metoidioplasty (mean = 13.0, SD = 10.2) groups; severe urologic symptoms were observed in 4 participants after phalloplasty and 2 after metoidioplasty (no differences between groups with and without urethroplasty). 24-hour voiding charts were available for 12 participants; mean daytime voiding frequency was 8.2 (4e10), mean nocturnal frequency was 1.1 (0-3), and mean total volume was 2,294 mL (740-5,100). On average, participants in the 2 groups were neutrally satisfied with their voiding function (phalloplasty: mean = 1.9, SD = 1.4; metoidioplasty: mean = 2.0, SD = 1.3;  $P > .05$ ). For sexual function, participants who underwent metoidioplasty reported significant higher sexual satisfaction (mean = 3.0, SD = 0.9) compared with participants who underwent phalloplasty (mean = 1.3, SD = 1.3;  $t_{16} = -3.0$ ,  $P = .009$ ).

## Motivations

All participants chose GCS to confirm their masculine identity. Other motives included enabling sexual intercourse, voiding, and bathroom and shower use. At follow-up, the surveyed transmen experienced (some or strong) positive contribution of surgery to their identity, voiding, and bathroom use, whereas lesser improvements were observed for sexual intercourse and discomfort with initiating relationships (Table 3). Phalloplasty was more frequently motivated by the wish to void while standing and easier access to male bathrooms and public showers than metoidioplasty. Also, participants reported significantly more improvements after phalloplasty on these items.

At follow-up, no participants regretted undergoing GCS, although 2 (1 with phalloplasty and 1 with metoidioplasty) mentioned they would have chosen an alternative type of surgery (eg, metoidioplasty instead of phalloplasty). Transmen felt that they were fairly well counseled before surgery by their surgeon (75%) and psychologist-sexologist (44%).

**Table 3.** Motives for genital-confirming surgery\*

	Motive before surgery	Improvement after surgery
Confirm masculine self-image		
Strongly	20 (100)	14 (70.0)
Somewhat or a little	0	6 (30.0)
Not	0	0
Enable active sexual intercourse		
Strongly	14 (77.8)	3 (16.7)
Somewhat or a little	3 (16.7)	9 (50.0)
Not	1 (5.6)	6 (33.3)
Enable voiding standing		
Strongly	14 (73.7)	8 (44.4)
Somewhat or a little	3 (15.8)	5 (27.8)
Not	2 (10.5)	5 (27.8)
Access to the men's bathroom		
Strongly	12 (66.7)	8 (44.4)
Somewhat or a little	3 (16.7)	6 (33.3)
Not	3 (16.7)	4 (22.2)
Discomfort in new relationships		
Strongly	11 (57.9)	6 (31.6)
Somewhat or a little	2 (10.6)	9 (47.4)
Not	6 (31.6)	4 (21.1)
Discomfort in saunas or public showers		
Strongly	7 (36.8)	3 (15.8)
Somewhat or a little	6 (31.6)	9 (47.4)
Not	6 (31.6)	7 (36.8)

\*Data are presented as number (percentage). Because of missing data and round-offs, percentages might not sum up to 100%.

## Psychosexual Outcomes and Quality of Life

The experienced postoperative quality of life was relatively good, with no significant differences from preoperative values and reference values (on the SHS and CL). The SWLS score was significantly lower than cisman values from the literature (Table 4). No significant differences from preoperative and reference values were observed on psychological measures of anxiety, depression, body satisfaction, self-esteem, and feelings of masculinity. Only satisfaction with hips was significantly lower in transmen compared with cisman reference values.

Findings on postoperative sexual activity indicated that participants engaged more in masturbation and sexual activity with a partner than before GCS. Also, when engaging in sexual activity with others, the genitals were more frequently used (31% before vs 78% after surgery; Figure 1). Furthermore, participants noted a change of sexual roles and experience after genital surgery, including more pleasure and confidence ( $n = 3$ ), a more passive role ( $n = 2$ ), and changed sexual orientation ( $n = 1$ ; from “exclusively to men” to “primarily to women”). The overall mean grade participants gave their sex life was 5.5 of 10 ( $SD = 2.6$ ). Motives for lower grades were “impossibility to penetrate/no erection prosthesis” ( $n = 5$ ), “not sexually active” ( $n = 4$ ), “penile size/sensation” ( $n = 3$ ), and “partner issues” ( $n = 2$ ). Average grades were lower in the group that was not sexually active with a partner.

**Table 4.** Pre- and postoperative quality of life and psychological well-being\*

	Preoperative	Postoperative	Reference value <sup>†</sup>	Test statistics	
				Pre vs post	Post vs reference
Quality of life					
SWLS	22.0 (6.5)	21.7 (7.1)	26.2	NS	t20 =-2.9, P = .009
SHS	4.8 (1.4)	4.6(1.5)	4. 9	NS	NS
CL	7.0 (1.5)	6.6 (1.5)	6.8	NS	NS
Psychological well-being					
HADS					
Anxiety	5.2 (3.1)	6.5 (4.3)	4.2	NS	NS
Depression	3.5 (3.2)	4.4 (4.6)	3.7	NS	NS
BIS					
Social and hair	—	2.2 (0.6)	2.3	—	NS
Head and neck	—	2.1 (0.6)	2.0	—	NS
Muscularity and posture	—	2.5 (0.6)	2.2	—	NS
Hip region	—	2.8 (0.7)	2.2	—	t19 = 3.5, P = .002
Chest region	—	2.8 (0.9)	2.3	NS	NS
Genitals	—	2.5 (0.8)	2.0	—	NS
RSES					
Femininity	30.5 (5.0)	30.6 (6.6)	32.4	NS	NS
Masculinity	1.6 (1.2)	1.6 (1.0)	—	NS	—

BIS = Body Image Scale; CL = Cantril Ladder; HADS = Hospital Anxiety and Depression Scale; NS = not significant; RSES = Rosenberg Self-Esteem Scale; SHS = Subjective Happiness Scale; SWLS = Satisfaction With Life Scale.

\*Values are presented as mean (SD).

<sup>†</sup> From van de Grift et al.<sup>3,5</sup>

## DISCUSSION

GCS is considered an important part of medical transition by many transmen, especially for those with genital dysphoria, the wish to penetrate, or the wish void while standing. Because different surgical techniques are available, much time is invested in preoperative decision making. Studies on technical outcomes after GCS in transmen have been published; however, much of the information on motives for surgery, experienced post-operative improvements, and overall psychosexual well-being and quality of life remains anecdotal. To our knowledge, the present study is one of the first longitudinal studies assessing these topics.

In the present cohort, FRFF-based phalloplasty was the most performed GCS technique. Similar (or higher) incidences of voiding, flap, and donor-site complications were observed compared with the (limited) literature.<sup>11</sup>

Fistulas and strictures are frequent issues after urethral lengthening, as are other lower urinary tract symptoms.<sup>12,13</sup> Metoidioplasty is considered a less extensive alternative to phalloplasty, which is reflected in the lower complication incidence<sup>11</sup> in the present study. Therefore, complications and subsequent secondary corrections should be an essential aspect of preoperative counseling.

In accord with the findings of others<sup>12,13</sup> we observed increased levels of lower urinary tract symptoms after (mostly urethral) surgery. IPSS scores were substantially higher than reference values, although severe voiding problems were uncommon. Possible explanations for increased levels of voiding symptoms include the high incidence of urethral strictures and fistulas. Although dissatisfaction with

voiding was reported infrequently, clinicians should be attentive to this subject during preoperative counseling and postoperative follow-up. This

awareness is particularly important because transmen might be unlikely to seek medical care for these issues<sup>12</sup> and these symptoms are associated with a lower quality of life.<sup>32</sup>

Decisions on GCS are preferably made based on individual goals, expectations, and physical characteristics. We observed that choosing GCS is a highly personal choice, because all participants (regardless of type of surgery) were motivated by confirmation of their (masculine) identity. The confirmation of one's identity appeared to pertain to esthetics (having a complete male-typical body) and functionality (the ability to engage in male-typical behavior such as penetration or voiding while standing). Similar topics have been reported before for gender-confirming medical interventions as a whole.<sup>6</sup> It is important that clinicians know that treatment motives can vary between persons, and even over time, and can assist transmen in this decision making. Weighing different outcomes (eg, voiding while standing vs complications after urethral lengthening) can be part of this. Also, partner and sexual preferences can be considered, in addition to individuals' socioeconomic status and the impact of long-term recovery from surgery. No data on this subject have been reported previously.

Sexual intercourse (78%) and engaging in relationships (58%) were considered important motives to pursue surgery. However, at follow-up, many reported only limited improvements. Also, sexual satisfaction was evaluated as relatively unfavorable. Experienced (quality of) sexuality might not change significantly directly after GCS compared with testosterone therapy only,<sup>23</sup> possibly leading to disappointment. This finding is something to consider in preoperative counseling. Also, erection prostheses are believed to contribute to sexual satisfaction.<sup>33</sup> In our cohort, no one had an erection prosthesis (yet), which could be another explanation for the lowered satisfaction (at time of study, erection prostheses were not reimbursed). The findings could have 2 possible implications: (i) clinicians should inform transmen that GCS might not directly result in a satisfactory sex life and (ii) ideally, (counseling on) erection prosthesis—recognizing the additional complication risks—should be part of transmen's health care. However, conclusive statements can be made only after assessing the study participants after erection prosthesis placement.

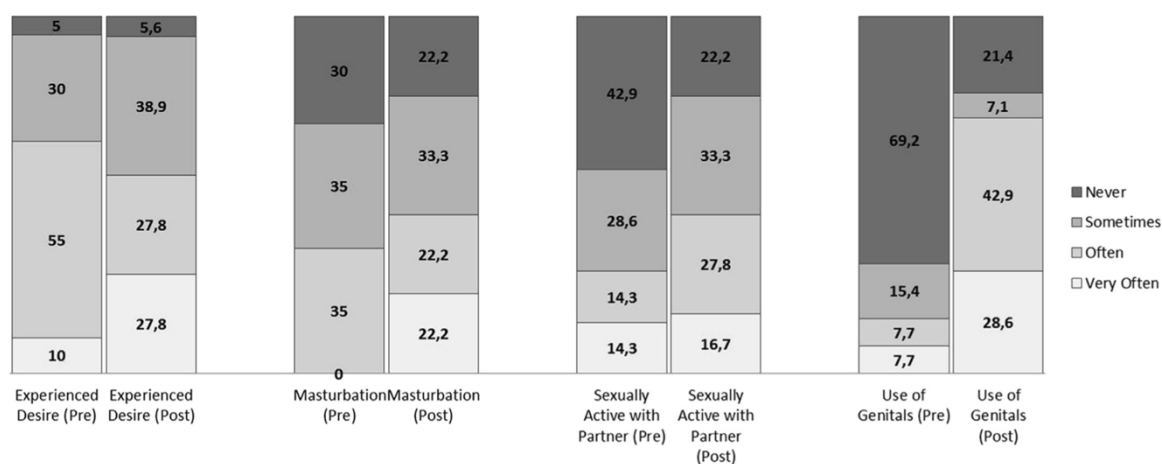


Figure 1. Sexuality before and after genital-confirming surgery. Data are presented as percentages.

Not all sexual satisfaction might relate to penile esthetics and function; free text comments indicated that not having a partner or having relational issues also affected the postoperative evaluation.<sup>34</sup> Therefore, postoperative (follow-up) counseling by a psychologist-sexologist can support transmen in how to experience satisfactory sexuality with the operated genitals. Currently, little is known about the postoperative sexuality of transmen; arousal and orgasmic capacity are likely to remain similar or improve.<sup>21,22</sup>

We also observed that engagement in sexual activities improves after surgery, including more involvement of and attention to the genitalia, possibly resulting in a more satisfactory sex life. Also, changes in sexual roles and orientation were observed (limitedly mentioned in previous studies<sup>34</sup>), which are important findings in the counseling of transmen before and during medical transition. Nonetheless, more explorative research is required to gain a better understanding in how (prior) social transition, testosterone therapy, and surgeries add to sexual quality of life. This also applies to motivations that have not been studied thoroughly.<sup>17</sup>

## LIMITATIONS

The present study was limited by its sample selection and size, follow-up time, and possible psychometric biases. The study sample was likely composed of a distinct group of transmen; participants were considered eligible for surgery, were motivated to undergo an extensive trajectory, and were willing to invest in a follow-up study. Therefore, the present study might not have included less functioning and/or less positive men. Also, the small sample might not have been able to detect minor (yet possibly clinically relevant) differences in the outcome measures. Similarly, the follow-up time might not have allowed us to detect improvements (or deteriorations) in sexual outcomes resulting from processes that are likely to take a longer time (eg, improved sexual self-esteem, placement of erection prosthesis, full physical recovery). Furthermore, some data were not collected (eg, on current gender) or collected using measures that were not validated for transgender-specific issues, possibly decreasing their sensitivity. Also, complex subjects such as sexuality and identity were only briefly assessed, leaving certain dimensions (eg, pleasure) and interactions (eg, with social status) beyond the scope of this study. The study method (recruitment



through surgeons and assessment by standardized questions) might not have grasped the complexity of sexuality after GCS. Further, transmen are known to report positive scores after genital surgery. Some of this effect might be explained by cognitive dissonance or social desirability.

## CONCLUSIONS

The standards of care for gender-confirming medical treatments such as GCS for transmen recommend decision making based on individual goals and expectations, yet little is known of their motivations and psychosexual outcomes. This study provides input for these clinical conversations and decision making. Important motivations for GCS pertain to identity confirmation, voiding, and sexuality. Although postoperative data on these subjects are generally positive (more sexual activity and more genital involvement), not all issues are resolved by surgery (eg, finding a sexual partner). Better decision making and realistic expectations might improve long-term outcomes.

## ACKNOWLEDGMENTS

The authors thank all study participants and Mieke Staphorsius and Anne Brewaeys for their contribution to the study.

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**Transmen's Experienced Sexuality and Genital Gender-Affirming Surgery: Findings From a Clinical Follow-Up Study**Tim C. van de Grift<sup>1,2</sup>, Garry L. S. Pigot<sup>3</sup>, Baudewijntje P. C. Kreukels<sup>2,4</sup>, Mark-Bram Bouman<sup>1</sup>, and Margriet G. Mullender<sup>1</sup><sup>1</sup>Department of Plastic, Reconstructive and Hand Surgery, VU University Medical Center, Amsterdam, The Netherlands<sup>2</sup>Department of Medical Psychology, Section Gender and Sexology, VU University Medical Center, Amsterdam, The Netherlands;<sup>3</sup>Department of Urology, VU University Medical Center, Amsterdam, The Netherlands;<sup>4</sup>Amsterdam Public Health Research Institute, Amsterdam, The Netherlands**ABSTRACT**

Genital gender-affirming surgery (GAS) aims to alleviate feelings of gender dysphoria and support psychosexual outcomes. However, little is known of sexual activity and satisfaction of transmen after phalloplasty or metoidioplasty. A clinical follow-up study was conducted in transmen at least one year after genital GAS in order to evaluate measures of experienced sexuality. Participants (N1/438) received a set of self-constructed questionnaires on sexual relationships and orientation, use of genitals during sexual contact, and the experienced influence of surgery on sexuality. Twenty-nine had received phalloplasty, nine metoidioplasty. The average follow-up time was 32 months. The majority reported to be sexually active. The use and enjoyment of both chest and genitals during sexual activity increased after surgery. Other areas of improvement included arousability, sexual interest, and pleasure. Free text comments provided an insight into the role of genital sensation and sexual self-esteem in postoperative sexuality. In conclusion, genital GAS positively impacts transmen's sexuality, although possible issues with genital sensation or penetration may exist and should be communicated preoperatively. Therefore, we recommend interdisciplinary collaboration on this subject.

**INTRODUCTION**

Gender dysphoria and associated body dissatisfaction may result in sexual issues. In recent years, a significant increase in referrals for gender-affirming medical therapies has been observed around the globe (Zucker, 2017). In essence, psychological, hormonal, and surgical interventions are provided to relieve mental distress and support satisfactory psychosexual outcome.

While for some aspects of psychological well-being, substantial research has been produced, indicating the effectiveness of genital gender-affirming surgery (GAS; phalloplasty or metoidioplasty; van de Grift, Elaut et al., 2017), little is known of the effects of surgery on sexual experiences of transmen specifically (Stephenson et al., 2017). Studies on postoperative sexuality of transmen are generally limited to frequency of sexual activity and masturbation (equally or more frequent than preoperative) and orgasmic ability (mostly able to achieve postoperative; Klein & Gorzalka, 2009). Other parameters of sexuality after phalloplasty have been studied in non-transmen populations only, albeit the lack of sufficient studies was pointed out here as well (Callens et al., 2013). With regard to providing an adequate preoperative informed consent and developing supportive follow-up services, the present clinical follow-up study was conducted focusing on sexual activity, orientation, and function.

**Table 1.** Experienced impact of genital GAS on aspects of sexuality, n (%).

	Increased	Similar	Decreased	Mean <sup>a</sup>
Arousability	10 (32)	20 (65)	1 (3)	0.29
Sexual sensation	14 (45)	12 (39)	5 (16)	0.29
Sexual pleasure	12 (40)	14 (47)	4 (13)	0.27
Interest in sex	12 (39)	14 (45)	5 (16)	0.23
Sexual initiative	8 (26)	18 (58)	5 (16)	0.10
Orgasmic intensity	8 (21)	16 (52)	7 (23)	0.03
Orgasmic capacity	7 (18)	16 (52)	8 (26)	-0.03

Due to rounding, percentages may not sum to 100; data available for 31 participants.

GAS = gender-affirming surgery.

<sup>a</sup> -1 = decreased, 0 = similar, +1 = increased.

## METHODS

A clinical follow-up study was conducted in 47 candidates who had received genital GAS surgery between 2011 and 2015 and were at least one year post-operation. Care was conducted in a center of expertise following the Standards of Care of the World Professional Association for Transgender Health (Coleman et al., 2012). Surgical procedures included phalloplasty and metoidioplasty with or without urethral lengthening. Preoperative counseling was conducted by a plastic surgeon, a urologist, and a psychologist-sexologist (e.g., on sexuality or possible penetrative ability after surgery). Everyone received similar surgical follow-up and no differences in background characteristics were observed between participants and non-participants.

Preoperative data on sexuality were collected standardly during the consultation with the psychologist-sexologist, and postoperative data were collected as part of this follow-up study. Participants (n=438, 81% of the recruited sample) received a set of (self-constructed) questionnaires assessing sexual relationships/orientation, the use of genitals during sexual contacts, and the experienced impact of surgery on sexual function (attached as Appendix A). Descriptive statistical analyses were performed. The research project was approved by the local ethical review board (van de Grift, Pigot et al., 2017).

## RESULTS

Participants were aged 40 years on average (SD = 10) and had on average received 13 years (SD = 8) of testosterone treatment at follow-up. In 29, a phalloplasty was performed (22 with and 7 without urethral lengthening; 15 FTFF, 2 ALT, and 10 ALT+FTFF flaps<sup>1</sup>); in 9, metoidioplasty (6 with and 3 without urethral lengthening); in all, mastectomy; in 18, testicular implants; and in 2, a penile implant. The average follow-up time after genital GAS was 32 months (SD=20). Overall satisfaction with genital appearance was 68% and with sexual functioning 36% ([strongly] agree on 5-point scale).

At follow-up, 28 reported they had a (sexual) partner (78%; 25 female, 3 male). Four reported sexual attraction (primarily) to men, thirty (primarily) to women, three to other than men/ women. Three participants reported changed sexual orientation after surgery (men to women, and unspecified to men and both). Most participants reported one (n = 21) or no (n = 9) sexual partners in the last 12 months. Sexuality was considered important by 82%. Comparing preoperative to postoperative data, the percentage of transmen who used their chest and genitalia during sexual contacts increased (chest: from 30% to 40%,  $p > .05$ ; genitals: 31% to 78%,  $p = .007$ ). The share of participants who enjoyed using these body parts increased (chest: from 22% to 50%,  $p > .05$ , genitals: 14% to 72%,  $p = .006$ ). A trend was observed with participants with metoidioplasty being more often (strongly) satisfied with their sexual function (63.5%) compared with participants who received a phalloplasty (28.0%;  $p = .09$ ).

Table 1 displays the experienced effects of GAS on aspects of sexuality. On average, most improvement was experienced on arousability, sexual sensation, and pleasure. A substantial minority, however, experienced a decrease (mostly regarding orgasmic capacity) and many reported no changes. Free text comments illustrated how sexuality related to phallic sensation: "I don't have much sensation in my penis, and orgasm is less as well." The neo-penis was experienced supportive in developing a positive self-esteem and masculine affirmation: "Surgery has made me more self-confident. Therefore I experience more gratification of my body and sex life," and as a result it was considered easier to engage in and enjoy sexual contacts: "I'm less confronted with being a 'woman.' I can easily let go during sex now." Still, some issues, mostly relating to penetrative inability because of absence of a penile implant, were reported. Some experienced feelings of insufficiency as a man toward their female partner: "My body is complete, but not being able to penetrate negatively impacts the sexual relation with my partner. It decreases my self-confidence, although my partner isn't to blame."

<sup>1</sup>ALT = anterolateral thigh flap, which is a sensate fasciocutaneous flap harvested from the thigh; FTFF = free radial forearm flap, which is a sensate fasciocutaneous flap harvested from the arm.

## DISCUSSION

GAS aims to alleviate feelings of gender dysphoria and support psychosexual outcome. This study aimed to add to the knowledge on the effects of genital GAS in transmen on sexual activity, orientation, and function. Most transmen experienced similar or improved sexual function after surgery. An important area of improvement includes one's gender affirmation. A finding that confirms other studies (Nikkelen & Kreukels, 2018; van de Grift, Elaut et al., 2017) observing positive associations among gender affirmation, body satisfaction and sexual outcomes. Also, participants experienced increased sexual initiative and sexual pleasure. This may relate to increased (sexual) self-esteem and affirmation of masculinity. These findings were supported by the free text comments as well. Phallic sensation and inability to penetrate were found to negatively impact sexual well-being. The first aspect may be related to the decreased orgasmic capacity, experienced by a significant minority of participants (possibly because genital stimulation is more difficult with a buried clitoris). This is important to consider when counseling trans- men on how they might develop pleasurable sex and how erogenous stimulation may have to be rediscovered (e.g., due to decreased sensitivity of the phallus). Also, for some transmen, penetrative ability may be more important after surgery than anticipated preoperatively. The inability to penetrate was experienced negatively as it conflicted with male-typical sexual roles and related to feelings of insufficiency. This was not unexpected, as only a few of the participants had received a penile implant. Earlier studies found improved sexual function after penile implants after phalloplasty (Young et al., 2017), while pain was reported as well (Wierckx et al., 2011). Therefore, a future study could follow up on the present group after implantation or compare the findings with cohorts who did receive these implants. Also, (improving) individual coping with surgical outcomes is important to consider in this context.

## LIMITATIONS

Although this is among the first studies on this subject, it was limited by its relatively small sample size, explorative questions, and short follow-up time. The design did not allow to differentiate among different treatment modalities. For some subgroups (e.g., those who underwent metoidioplasty or a phalloplasty without urethral lengthening), a larger sample size (e.g., 20 participants per subgroup) would have made the outcomes more generalizable. Also, as participants were already on testosterone therapy, we only studied the effects of surgery. No outcome data on non- participants were available, and several outcomes had significant missing data. Moreover, no validated measure of sexual well-being is available to follow up on transgender individuals. Most instruments are sex-specific (i.e., pre- and postoperative comparisons are not possible) and/or based on heteronormative sexual activity (i.e., penetrative sex is assumed). Therefore, we plea for the development of transgender-inclusive measures of sexuality. Also, we emphasize the need for broader understanding of other factors, such as socioeconomic- and mental health-related factors, in surgical decision making.

## CONCLUSION

Our findings can assist clinicians in their informed consent regarding genital GAS; surgery can positively influence sexual experiences, and changes in sexuality may occur (e.g., changed sexual orientation), yet decreased sensation or inability to penetrate are prevalent as well and may decrease sexual outcomes. In order to improve psychosexual outcomes of surgery, we recommend collaboration between surgeons and psychologist-sexologists, both in preoperative counseling and in postoperative follow-up. Such collaboration may focus on informing transmen on opting for penile implant surgery versus developing satisfactory non-penetrative sexual strategies.

## ACKNOWLEDGEMENTS

The authors would like to thank all study participants, as well as Siham Boudhan, Marlon Buncamper, Lian Elfering, Luk Gijs, Eric Meuleman, Mujde Ozer, Wouter van der Sluis, and Mieke Staphorsius for their contribution to the study.

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## Appendix A. Follow-up survey questions on sexuality

Question	Answering options
To whom are you sexually attracted?	Modified Kinsey scale

Has your sexual attraction changed as a result of your genital surgery?	Yes No
How many sexual partners have you had over the past year?	n/a
How important is sexuality for you?	Important Not so important Unimportant
How frequently does your partner touch your chest during sexual activity?	Never Sometimes Often Always
Did you enjoy this?	Never Sometimes Often Always
How frequently does your partner touch your genitals during sexual activity?	Never Sometimes Often Always
Did you enjoy this?	Never Sometimes Often Always
How did genital surgery impact the following aspects of your sexual life?	Increased Similar Decreased
Arousability	
Interest in sex	
Orgasmic capacity	
Orgasmic intensity	
Sexual initiative	
Sexual pleasure	
Sexual sensation	
Can you briefly elaborate whether/how your genital surgeries have influenced your sexual life?	n/a

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## GENERAL DISCUSSION AND FUTURE PERSPECTIVES

Gender affirming care for persons experiencing an incongruence between their gender identity and their physical sex, is expanding and the number of individuals seeking help has been increasing during the last decade. This growth requires changes in the organization of health care. Due to the many different aspects of the treatment (e.g. psychological counselling, urological counselling and hormonal and surgical therapies), this care is complex, and demands a well-coordinated multidisciplinary approach. In addition, there is more diversity in treatment requests as well as in treatment options, and there is a trend towards more individualized care. In order to match treatment with the individual wishes, the need for shared decision making has been given much emphasis.

As stated in the introduction, the final phase of gender affirming care (for those wishing for it) is genital surgical treatment. Genital gender affirming surgery (gGAS) in transgender men can broadly be divided into 3 stages. During the first stage female sexual characteristics are adjusted, resected or removed (breast amputation also referred to as top surgery, salpingo-oophorectomy-hysterectomy and colpectomy). In the second stage masculine external genitalia are created which is referred to as genital Gender Affirming Surgery (gGAS) or bottom surgery. The third stage consists of implantation of prostheses (penile and/or testicular implants). Each of these surgical procedures pose their specific challenges reflecting the complexity of surgical gender affirming treatment.

At the VU University Medical Centre the urologist is involved in the second and third stages of the surgical treatment.[1] Both the surgeon and the transgender individual are confronted with challenges and the complexity of care. Challenges include the technical difficulties of the masculinizing surgery, in order to create a genital with satisfying esthetical features, adequate functional outcomes regarding sexual function and voiding, and prevention and managing of complications. The most challenging requests faced by the urologist are the wish to urinate from the tip of the constructed phallus, and the wish to be able to have penetrative sexual activity. To date, the complication risks involved in urethral lengthening and placement of implants (mainly penile implants) have been high.[2] Additional challenges with regard to GGAS include determining the type of GAS (phalloplasty or metoidioplasty), urethral lengthening and prosthetic insertion.

This thesis elaborates on 3 topics regarding the surgical phase of the masculinizing process in which the urologist is involved. These topics are: counselling on and management of possible complications related to (1) urethral lengthening and (2) implantation of prosthetics and (3) the development of a decision aid (which type of GAS?) based on the outcome of PROMs on sexual functioning and well-being following the surgery.

## PART ONE

Addressing urological complications in gGAS

The majority of transgender men prefer gGAS with urethral lengthening (UL) enabling them to void while standing. gGAS with UL can change voiding habits: emptying the urethra by pushing on the perineum and scrotum to prevent post void dribbling is common. [3,4] High rates of urethral fistulae and urethral strictures are reported after gGAS. [5,6,7,8] Urethral fistulae occur due to dehiscence of parts of the neo urethra. Urethral strictures predominantly occur at the pars fixa and pars pendulans anastomosis. It is thought that ischemia at the anastomosis leads to fibrosis resulting in a urethral stricture. Recurrence rates are high after treatment of these urethral fistulae and strictures. Several adjustments have been made to reduce these complications, of which performing a colpectomy before gGAS with UL in our hands has shown to be effective in decreasing the number of neourethral fistulae.[9,10,11]

Another measure to prevent urethral complications is depilation of the urethral donor site in case of excessive hair density. It is known that hair in the urethra can form hair balls and calculi causing obstructive voiding and necessitating an intervention.[12] Although depilation has been offered for decades its outcomes have never been specifically assessed in transgender men. Moreover, urological complications due to intra urethral hair growth after phalloplasty's with UL have never been published.

In **chapter 2** outcomes (surgical, urological, functional and patient reported outcome measurement (PROM)) are presented after gGAS without lengthening of the urethra. It has been postulated that refraining from UL during gGAS would reduce urethral strictures and urethral fistulas, and thus would reduce the number of post-operative complications. In this study, an overall post-operative complication rate of ten percent was recorded which is significantly lower than that (20-70 percent) after gGAS with UL.[5,6,7,8] Another benefit of gGAS without UL is the use of only a trans urethral catheter (TUC) post operatively, in contrast to the suprapubic catheter (SP) and TUC used after gGAS with UL. In addition to this, the TUC is removed during hospital admission at post-operative day 4-5 whereas for gGAS with UL transgender men leave the hospital with both (SP and TUC) catheters. Results from the PROM show that around sixty percent of transgender men were satisfied or very satisfied with the aesthetical outcome, and around forty five percent with the functional outcome. In addition, there were no transgender men who regretted the operation. In case of regret of gGAS without UL, lengthening of the urethra is challenging as all the tissue to create the pars fixa has been resected. These outcomes are partly due to the extensive pre-operative counselling, and indicate the importance of the pre-operative counselling process.

**Chapter 3** deals with surgical technique of the gGAS without UL. This is a one staged technique in which scrotoplasty as developed by Hoebeke and Monstrey is combined with phalloplasty [13]. We found this technique to meet the expectations for phalloplasty's as described by Hage except for voiding from the tip of the phallus.[9]

**Chapter 4** presents outcomes of effectiveness of pre-operative urethral donor site laser depilation, and on the correlation between urethral hair density and voiding among transgender men undergoing phalloplasty with UL. Data from this study show that depilation resulted in a reduction of hair but not complete hairlessness. Transgender men with high and moderate hair density level were most frequently depilated and the average number of laser sessions was 6. In this study no hairballs or calculi occurred. In general and in correspondence with the literature it can be stated that depilation does not result in complete hairlessness, and that hair growth in the neo-urethra does not cause voiding complaints. The reduction of hair after depilation is in line with earlier publications on laser depilation on other sites of the body in

cis gender patients.[14,15] Although some transgender men presented with high and moderate hair density levels in the neo-urethra after depilation no hair balls or calculi were seen probably because the short follow-up time.

#### Future perspectives aiming to reducing post-operative urological complications

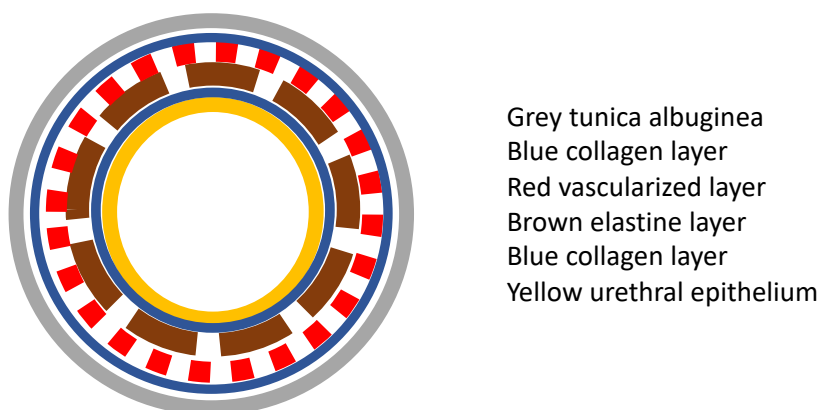
Despite all the advantages and benefits of gGAS without UL, many transgender men consider voiding from the tip of the phallus important, and the risk of complications which come with gGAS with UL acceptable. From daily practice we know that transgender men are willing to go to great extent to achieve the possibility of voiding from the tip of the phallus. These facts cause a need for improvements and adjustment of the surgical technique with the aim to reduce post-operative complications after gGAS with UL.

A way to reduce surgical complications may be to create a neophallus with urethral lengthening in two stages. To date, in the VU University Medical Centre this is still being performed in one stage. To make a switch to a staged approach our surgical protocol for gGAS with UL should be adjusted especially with respect to the timing of the tubularization the neo-urethra, because complications predominantly occur at the neo-urethra, and more specifically at the pars fixa and pars pendulans anastomoses. The two-stage protocol for gGAS with urethral lengthening will consist of the known steps e.g. reconstruction of neo-scrotum with the pars fixa combined with the reconstruction of the phallus with the pars pendulans. In addition, instead of connecting the pars fixa and pars pendulans in an end-to-end fashion, a scrotal urethrostomy or scrotostoma will be reconstructed by dorsal connection of the pars fixa to the pars pendulans, omitting to ventrally close the anastomosis. Besides this, the ventral part of the pars fixa and pars pendulans will be spatulated and sutured to the ventral part of the scrotal skin. In this way a wide scrotostoma is created. A suprapubic catheter and trans urethral catheter are inserted during surgery. The trans urethral catheter is removed 2 weeks post-operatively, and the suprapubic catheter at least one week thereafter if possible. Ideally closure of the scrotostoma is at earliest 3 months after the first stage with the placement of only a trans urethral catheter. This can be removed after 2 weeks if the anastomosis has properly healed. Closure of the scrotostoma can then be combined with the insertion of testicular implants, and or with a glansplasty.

Multiple procedures are necessary after gGAS with UL in one stage to reach the end result because of post-operative complications and the wish for prosthetics. It is unknown whether the one stage or multiple staged procedures give better results with concern to number of necessary operations, complications rates, aesthetical and functional outcomes and post-operative satisfaction. With regard to this, future studies need to focus on developing the ideal surgical protocol and assess outcomes of staged procedures preferably in comparison with the one stage procedures.

As for the urological complications, it has already been stated that ischemia at the pars fixa pars pendulans anastomosis is seen as the cause of stricture formation.[16] Assessing blood flow at the edges of the pars fixa and the pars pendulans per-operatively can help to identify the well-perfused parts. This allows the poorly perfused part to be removed and the well-perfused parts to be used for the anastomosis. A recently introduced method to assess tissue perfusion intraoperatively is the use of indocyanine green (ICG) fluorescent angiography.[17,18] Incorporation of this technique in the gGAS with UL protocol may be an aid to choose the best perfused parts of the pars fixa and pars pendulans.

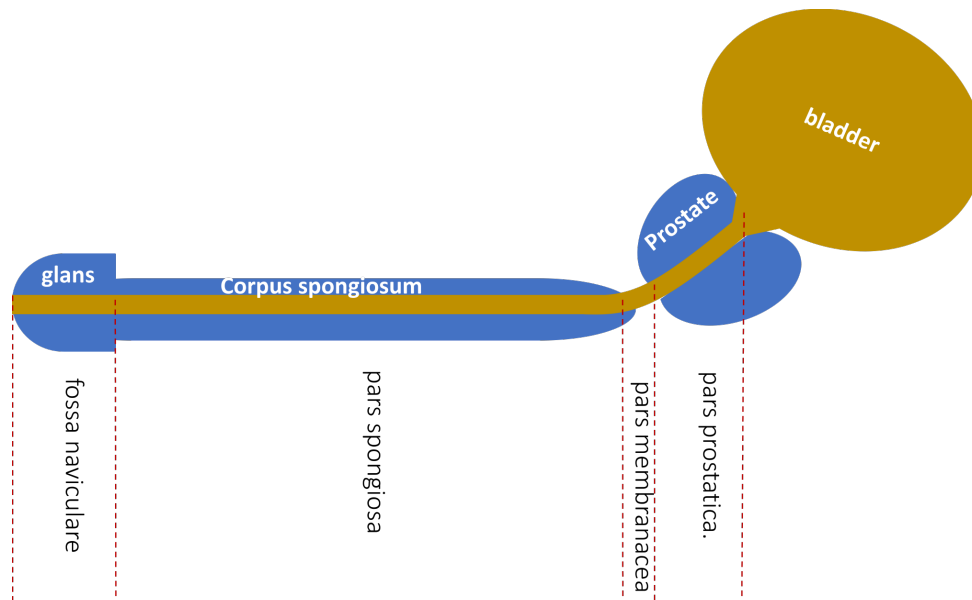
An area that can contribute to improving gGAS in the future is tissue engineering (TE). Using cultured male external genitals during gGAS that contain biological structures of the penis and scrotum, can have a major impact on the surgical phase of the transition pathway. However, the use of 'off the shelf' male external genitals, is not feasible in the near future. Amongst other things, technical difficulties in culturing organs with vascularity and innervation make it difficult to achieve this.[19] It seems rather feasible to culture parts of the male's external genitalia, such as parts of the urethra. Most neo-urethras being reconstructed during the gGAS are pedicled flaps. The inner lining of these neo-urethras consists of skin surrounded by fat containing the pedicle (pars pendulans) or from the labia minora (pars fixa). Techniques using graft to reconstruct part of the neo urethra are also known. These neo-urethras, however, do not resemble the urethra of a cisgender man with respect to anatomical structures and function. The urethra in cis gender men is part of the corpus spongiosum (CS). Recent publications show that four layers can be distinguished in the CS (not including the urethral epithelium and the tunica albuginea); from the urethral lumen first a highly vascularized, collagen rich layer is followed by a second, elastin rich layer. The third layer is formed of veins, arteries and vascular spaces, covered by endothelium and the last outer layer is the transition from this vascular rich region to tunica albuginea which consists of collagen bundles in a wave-like structure intertwined with short elastic fibres.[20] (figure 1)



**Figure 1** cross section of the cis male urethra at the pars spongiosum



From the bladder to the urethral meatus, the male urethra can be divided into three parts. The first short proximal segment is surrounded by the prostate, and is called the pars prostatica. It is lined with urothelium of the same type as that of the bladder. The second very short segment is called the pars membranacea, and extends from the apex of the prostate to the bulb of the CS penis. It is lined with stratified or pseudostratified columnar epithelium. The third portion, called the pars spongiosa, has a length of about 15 cm, and is also lined with stratified or pseudostratified columnar epithelium, but patches of stratified squamous epithelium are common in the pars spongiosa. Stratified squamous epithelium is also found in the terminal widened part of the canal that is surrounded by the glans penis, the fossa navicularis.[21] (figure 2)



**Figure 2:** overview of the cis male urethra

From these studies we learn that the urethra is composed of different types of cells and structures in addition to being tubular. These characteristic and spatial organization make it difficult to engineer a urethra in its biological form in the lab.

Tissue engineering (TE) is defined as an interdisciplinary field applying the principles of engineering and life sciences toward the development of biological substitutes that restore, maintain, or improve tissue function or a whole organ.[22] In tissue engineering, techniques and combinations of cells, material methods, and appropriate biochemical and physicochemical factors are used. These techniques involve the use of autologous cell cultures, and of scaffold to form new viable tissue for a medical purpose. There has already been experience with tissue-engineered scaffolds, cell-seeded scaffolds and autologous cell cultured grafts to create single layered and multiple layered flaps and tubes to perform urethral reconstructions in animals, and cis gender male patients with urethral stricture disease.[21,23] Meta-analysis of preclinical (animal) studies show that for full circumferential urethral repair, the addition of cells to the templates significantly reduces the probability of urethral strictures or fistulae. In clinical studies decellularized, acellular and cell seeded scaffolds have not shown statistically significant difference as for urethral strictures and fistulae.[23] These outcomes, however, come from low quality preclinical and clinical studies, and much research remains to be done, for example addressing the type of scaffolds, type of cells, spatial organization of tissues etc. With regard to gGAS a first step would be research on the viability of an engineered urethral plate in the neophallus. A next step would be to assess patency, and stricture rate following tubularization.

As for hair containing urethras, men with these urethras may have a higher risk of developing hair balls and hair calculi. Daily practice learns that application of intra urethral hair removal cremes are advised, and that hair removal is performed by urethroscopy. Results regarding hair density, and prevention of hairballs and calculi formation after these treatments are unknown. Clinical relevance of this problem is unclear. Hence it is difficult to develop proper treatment and follow up regimes. Future studies on treatment modalities for intra urethral hair can aid in the development of these regimes.

With this study a classification system is developed to score pre-operative donor site hair density helping to assist in depilation. A shortcoming of this classification system is that it only assists in the indication process. A classification forecasting results of depilation would be better, but setting this up is challenging as many factors influence the depilation effect such as skin type, hair type, laser type and laser time. This study does not define the exact role of pre-operative donor site depilation. To sort this out a randomized study should be conducted, which compares individuals with and without (different types of) depilation and taking into account the different aforementioned factors (skin type, hair type). Besides the effects of the laser depilation on hair density long term follow up assessing formation of hairballs and calculi is also of interest. Randomization, however, is difficult due to the many patient dependent factors known to influence results. As a result such a study would demand a high number of patients and will be time consuming. Ultimately, it is questionable whether these difficulties will outweigh clinical relevance.

## PART TWO

### Outcomes of prosthetic surgery in transgender men after gGAS

In the second part of this thesis the topic of prosthetics after gGAS in transgender men has been addressed. As mentioned earlier this is most of the time the last phase of the surgical part of the transition.

**Chapter 5** gives an overview of the testicular implants used at the VU University Medical Centre and the data reflect our experience in this field. Testicular implants serve to augment the neo-scrotum, and developments in this field have been mainly changes in the implanted products itself. Over the years, and partly due to a change in our scrotoplasty technique a shift in type and size of testicular prostheses has been observed. The combination of a novel scrotoplasty technique, secondary implantation of the testicular prostheses, and the use of smaller implants has caused a reduction in complications of 10 percent. Complications mostly occurred in the first month after implantation. A history of smoking appeared to be a major risk factor for explantation.

**Chapter 6** reports the long term experience in the VU University Medical Centre with different types of penile prosthetic implants after phalloplasty. The data show a transition towards the use of malleable instead of inflatable implants. Partly, this transition has been driven by the fact that until recently penile implants have not been reimbursed by health insurers and most patients preferred the relatively cheaper malleable prosthesis. A limitation of the study is that the small number of included patients does not allow to answer some of the relevant clinical questions.

**Chapter 7** presents the initial results of a new malleable device specifically developed for phalloplasty's (ZSI 100,ZSI 100D13). This mono cylinder malleable prosthesis is easy to fixate to the pubic bone, and it is rigid enough to have penetrative sexual intercourse. There are two options with regard to the girth of the implant, which are both easy to adjust in length.

A high complication rate resulting in an explantation rate of 44 percent was recorded. This was probably due to the learning curve and the relative short experience with the new device. The fact that a total flaccid state is not possible, due to the intrinsic rigidity of the prosthesis, showed to cause problems in wear ability and social activities. Some transgender men experienced difficulty in bending the phallus and this caused limitations during sports, swimming or going to the sauna.

### Future perspectives

Prosthetics (testicular and penile) will continue to hold a place in gGAS in transgender man in the future for both aesthetic and functional reasons. The testicular implants have an aesthetic function by augmentation of the scrotum. Nowadays we augment the neo-scrotum during scrotoplasty with two pedicled prepubic fat pads, which are caudally trans positioned. These serve as a well vascularized cover for the future implants. Because scrotal filling with this technique is satisfactory for some transgender men further augmentation of the neo-scrotum with prostheses is not desirable anymore. So far, no post-operative complications of this step have been encountered. Widespread applicability of this scrotal augmentation technique (surgical outcome, patient satisfaction, number of transgender men refraining from testicular implants) should be further investigated in future studies.

Data on the effects of scrotoplasty and neo-scrotal augmentation on gender dysphoria, masculinity and post-operative satisfaction are scarce. For example, do the size of the neo-scrotum and the size of the testicular prostheses matter? PROMs can help to conduct studies concerning these topics. Results from these studies on the other hand can aid in formulating and further developing validated PROMs.

Penile implants affect aesthetics, psychology and functioning, and the ability to have penetrative sexual intercourse. The wish for a penile implant is a consequence, amongst other things, of not feeling masculine and hence being reluctant to engage in sexual contacts.[24] Counselling by the urologist and, since 2017, counselling by a sexologist before implantation of a penile prosthesis has been mandatory in the Netherlands. The urologist mainly addresses surgical aspects (e.d. procedure, post-operative complications) and the sexologist focusses on sexual functioning and expectations of sexual functioning following implantation of a penile prosthesis. This is considered important in order to enable the patient to balance the pros of a penile implant (the ability to have penetrative sexual intercourse) against the cons (high risk of complications) and make a well-founded decision. To date, counselling by the sexologist has been hampered by the scarcity of prospective studies on sexual functioning of transgender men.[25,26,27] Therefore, we intent to include a post-operative sexual counselling session in our protocol to gain insight in sexual functioning of transgender men having undergone a phalloplasty. This will help to improve the preoperative counselling process and will contribute to personalized care. By analogy with the data collection of the European Network for Investigation of Gender Incongruence (ENIGI), these data should be collected in an international data bank.[28] This will enable analysing outcomes which will also lead to better counselling of transgender men.

With regard to the choice of type of penile implant, the following needs to be taken into account:

it is convenient to implant with low post-operative complications and re-operative rates

it mimics normal penile physiology with concern to rigidity and flaccidity

it is easy to handle without limitations in social activities and enable transgender men to have the preferred sexual intercourse.

Experience has learned that phallus dimensions and sensation, and social and sexual activities, but also comorbidity should be taken into account when deciding on the type of penile implant.

It is also well known that phallic sensation is of importance for a satisfying sexual experience.[29] Additionally, it is thought that phallic sensation has a protective role for penile implants, mainly because one can feel what he is doing and therefore also feel when things are not going well. At the VU University Medical Centre phallic sensation is attained by coaptation of the dorsal clitoral nerve (a branch of the pudendal nerve) to the sensory nerve in the shaft of the neophallus. Three different flaps for the construction of the neophallus have been used; all with their own innervation: (1) The free radial forearm flap (FRFF) innervated by the lateral and medial antebrachial cutaneous nerves, (2) the anterolateral thigh flap (ALT) innervated by the lateral cutaneous femoral nerve and (3) the superficial circumflex iliac perforator flap (SCIP) innervated by the intercostal nerves (10,11 or 12). The FRFF is the flap with longest follow up followed by the ALT.[29] The innervated SCIP has been in our armamentarium since 2017. In 2015, we have started to study innervation of phalloplasty's using the Semmes

Weinstein monofilaments sensory assessment tool, in order to assess the return of sensation over time following phalloplasty.[30] During sensory assessment the contra-lateral donor site is used as reference. The data of this study will also enable comparing innervation between the different flap types. Moreover, they can aid with respect to the timing of implantation of penile implants. As being hypothesized in this study neo-phallic sensation has a protective role for penile implant and therefore diminishes prosthetic perforation. Until these data are available, the practice is to implant a prosthesis at earliest 1 year following phalloplasty presuming that optimal reinnervation of the neophallus has been reached.

In the study of the ZSI 100 malleable penile implant, complication rates show similarity with previously published data on penile implants in a phalloplasty. Literature, however, mostly comprises data of inflatable prostheses which makes it difficult to compare outcomes.[31] Worth mentioning are the lower complication rates of the novel inflatable prosthesis (ZSI474 FTM) especially developed for phalloplasty's.[32] This implant consists of a single cylinder, a reservoir which is placed in the cave Retzius, and a pump mimicking a testicular implant. In addition the proximal part of the cylinder is connected to a fixation plate to secure the implant to the pelvic bone (figure 3).

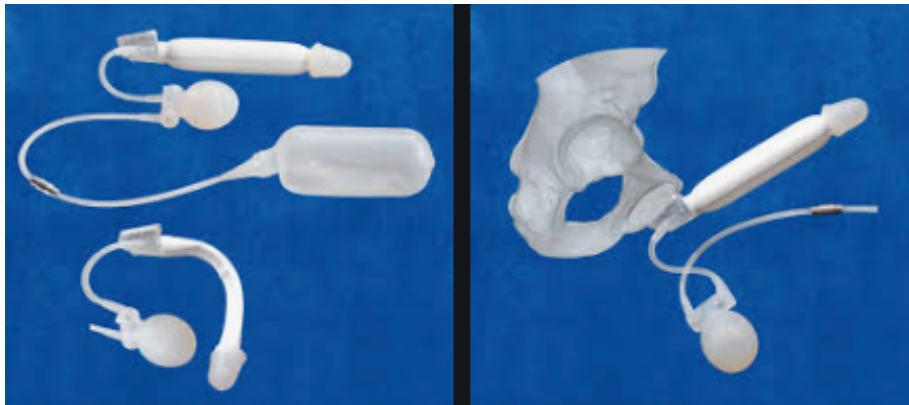


Figure 3 ZSI 475 hydraulic penile implant.

However, the limited number of patients and follow up time need to be taken into account when interpreting outcomes.[32] The experience with the malleable (ZSI100) and inflatable (ZSI475) implant is increasing. Multi-institutional studies are needed to assess surgical outcomes and post-operative functioning, and satisfaction in these two groups. Long term follow-up of sustainability, re-operation rates and complications is needed. Additionally, comparing these outcomes with the outcomes of transgender men who have the cis gender men penile implants will give insight in whether these newly developed implants are an improvement.

Meanwhile, the inflatable prosthesis will be the implant that fulfils most of the above mentioned criteria for the majority of patients. Still further developments of the implants are important. For example, the development of a reservoir that can be placed in the scrotum through the incision used to place the prosthetic cylinder(s). This would make a separate incision to access the extraperitoneal space unnecessary. Another field of interest for research and development is the mechanism to induce rigidity and flaccidity of the implant. Nowadays this is achieved by a hydraulic pump which must be pressed. Changing this into an electric mechanism would improve handling and may influence durability of the system. Experience from cardiac medicine where cardiac resynchronization therapy pacemaker (CRT-P) using long lasting batteries can aid in these developments.

### PART THREE

#### Shared decision making and patient reported outcomes after gGAS

The challenges facing the surgeon and the transgender man emphasize the importance of thorough counselling, aiding the shared decision making process with concern to gGAS. To facilitate this process a decision aid (DA) for genital surgery in transgender men (DA-GST) has been developed (**Chapter 8**). This aid enables transgender men to weigh personal preference and risk of complications in order to make a deliberate decision. Feed-back from transgender men suggests that it is a useful and valuable tool in the decision making process.

**Chapter 9 and 10** Psychosexual outcomes and quality of life after gGAS were assessed combined with the assessment of the motivation for gGAS. A self-constructed PROM was used. Psychological measures (anxiety, depression, body satisfaction, self-esteem, feeling of masculinity) and quality of life remained the same after gGAS. An increase in sexual activity has been observed, and an improvement in the use and enjoyment of the chest and the genitalia during sex. Absence of a penile implant and the inability to have penetrative sexual intercourse caused restraint with initiating relationships after phalloplasty, and lowered overall satisfaction. A decrease in orgasmic function has also been observed after phalloplasty's. The impaired orgasmic function may be due to anatomical changes causing the clitoris to be buried at the base of the phallus, and being less accessible. While transgender men chose gGAS for various personal reasons, conformation of their male gender identity had been the main reason to advance to this surgical phase of the transition trajectory. No regret after gGAS was noted post-operatively, although 2 patients mentioned that they would have chosen a different type of gGAS.

The results of the two studies show the impact and importance of gender affirming treatments, and the role that masculinizing surgery plays in the process of adapting physical characteristics to the experienced gender. The data also revealed that for a number of patients gGAS as such did not alter their psychological well-being. These outcomes suggest that psychological counselling, hormonal therapy and/or mastectomy combined with a male gender role already increase the psychological well-being, and have a positive effect on gender dysphoria in a specific group of transgender men. So, for those individuals the surgical phase adds relatively little to general psychological well-being, but provides for specific sexual, urological and body image needs. These findings indicate the importance of addressing post-gGAS expectations

during the pre-operative counselling process. Systematically collecting and analysing these data can aid the shared decision making process and help evolve the gender affirming process towards a more individualized care.

### **Future perspectives**

The process of developing a prostate cancer decision aid at our institution has been used as an example to set up a specific decision aid for genital surgery in transgender men.[33,34] Feedback from transgender men suggests that this aid, that ideally is completed together with a health care provider, is of added value in making a decision with regard to the type of gGAS. The involvement of the health care providers will increase the experience in using the aid during consultations to maximize its value. Systematically collecting and assessing data with regard to the aid will enable to ascertain its value and applicability and can help to improve it and determine its position in the preoperative counselling. The alterations and possibilities occurring in the affirming process (e.g. preservation of germ cells) and the changes in demands of transgender men (e.g. which for only hormonal therapy and thus refraining from surgery; wish to conceive) are factors that need to be taken into consideration to fine-tune the aid, and to decide on the timing of its use in the transitory process. For example, it could be introduced after completion of the diagnostic phase, before the start of hormonal therapy. In this phase it would be used more as a guide giving an overview of the treatment options and the consequences associated with the different treatment steps. A disadvantage of introducing it at this point could be that the information is overwhelming and may cause confusion.

Translation in different languages can follow after the aforementioned steps keeping in mind that the aid is based on the gender affirming pathway in offered at the VU University Medical Centre. As a consequence, the translation and validation process needs to be revisited when the aid is used in other centres, as parts of the pathway may differ from one centre to the other.

Results from the PROMs are of importance as they help guide physicians in the development and adjustments of medical care based on patients experiences. In gGAS for transgender men these PROMs have to address specific issues being relevant to them. These most likely include aesthetic and functional outcomes and donor site morbidity on the one hand, but also the need of reflecting on psychological and psychosocial outcomes on the other hand (e.g. effect of gGAS on gender dysphoria, sexual functioning, feeling of masculinity, expected and experienced outcomes, social functioning like work and sports). All of the outcomes eventually contribute to the general, and health related Quality of Life (QoL). Clinical experience and the scarce literature suggest that medical care effectively reduce feelings of gender dysphoria and improve body satisfaction.[35] There are various reasons why transgender men opt for gGAS and a masculine genital appearance, voiding while standing, enabling the wearing of tight shorts, and sexuality play a role in the decision making.[36] The limited size and the retrospective analysis of the data presented in chapter 9 and 10 along with the fact that non validated questionnaires were used, limits the level of evidence retrieved from the PROMS. Still the results are largely in line with the literature at present, and give insight in the effect of the masculinizing surgical interventions on gender dysphoria.[37] This allows the use of the outcomes in the pre-operative counselling process and also gives direction to future studies. These future studies should aim at developing a validated multilingual questionnaire. Collaboration between gender centres and patient associations will help to accomplish this.

Prospective data collection can aid in improving pre-operative counselling. Such initiatives can also provide understanding of characteristics and surgical needs of 'upcoming' gender dysphoric groups such as genderqueer or non-binary individuals. As surgeons tend to think predominantly in a binary fashion, little experience is gained with non-binary individuals. In practice, the number of non-binary individuals consulting gender surgeons is small, probably because GAS has little influence on gender dysphoria in this group of individuals. The small number of non-binary individuals seeking GAS and the limited experience of the gender surgeon with this group of individuals emphasizes the importance of a sound multidisciplinary approach in order to best meet these individual needs.

Nowadays the PROMs are used as a separate tool besides medical records. A future step is to intergrade these PROMs into electronic medical records, and use them as a part of the medical care. Using collective data, extracted from these PROMs, and making this available in medical records can help in making care more efficient, and can assist in further improvement of this care. Ideally an individual should be able to log into his charts from outside the hospital and have all the information covering all the aspect of the affirming process, and having displayed outcomes at a central part of the chart.

### **CLOSING REMARK**

During gender affirming therapy of transgender men hormonal and surgical therapies are used to masculinize the body. This complex process requires solid provision of information to the transgender individuals and adequate communication amongst care givers, and most importantly between care givers and care takers. Outcomes obtained by clinical research are the foundation for adequate reliable information provision. This thesis has addressed topics of the genital surgical phase of the affirming process in which the urologist has a central role, and is responsibility for the outcome. This thesis contributes to evolving the transgender care towards more evidence-based care, that weighs the pros and cons of each step in the transition process meticulously. The results of these studies, however, also show that there is a great need for more clinical research. May this thesis further light the fire of enthusiasm for future research in this field.

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## Chapter 12

### Summary

The genital surgical phase of the gender affirming process in transgender men can alter the urological anatomy and urological function. This advocates urological involvement during this phase of the affirming process. The urology department is part of the gender team of the VU University Medical Center since 2013 and it is responsible for functional outcomes e.g. voiding and sexual function. In order to be able to perform this function we are part of the surgical team during the gGAS (reconstruction of the neo-scrotum and the neo-urethra during the phalloplasty, the reconstruction of the neo urethra during metoidioplasty) and carry out procedures independently (insertion of testicular and penile prosthesis, perform urethroplasties and secondary corrections). In addition to physical effects, the results of these operations can also have psychological and socioeconomic consequences. In addition to this, it is important that the results of these operations are properly maintained and analyzed. This thesis is divided into three parts describing respectively: measures taken to prevent postoperative urological complications after gGAS, experience and results after implantation of prostheses, the development of a decision aid and results of psychological and sexual functioning and well-being after gGAS. All areas where urological involvement is required.

### Introduction

The first part of the introduction provides an explanation of gender care. The rest describes the structure of the thesis.

#### Part 1

Part one covers adjustments made to reduce urologic complications after gGAS in transgender men. In **chapter 2** functional and surgical outcomes, and patient satisfaction are described after genital gender affirming surgery (gGAS) without urethral lengthening (UL). Sixty eight transgender men were included in this study. The International Prostate Symptom Score (IPSS), uroflowmetry and 24 hour frequency voiding chart (FVC) were used to assess functional outcomes (storage and voiding function). A self-constructed semi-structured questionnaire was used as a patient reported outcomes measure (PROM). Median follow-up time was 24(6-129) months. Postoperative surgical and urological complications occurred in respectively 9(13%) and 8(11%) patients. Storage and voiding function remained unchanged. The median quality of life (QoL) due to urinary symptoms scored as "pleased". Sexual functioning and voiding scored "satisfactory" and "very satisfactory" in respectively 18/40(45%) and 21/40(53%) patients, while 25/40(63%) were satisfied with the penis, and 26/40(65%) marked off "very satisfactory" with the neo-scrotum, 32/40(80%) reported an increased self-esteem, 32/40(68%) would undergo the surgery again, and 28/40(70%) would recommend it to others. The outcomes of gGAS without UL, shows good surgical and urological results. After extensive counseling the majority of this selective group of patients shows favorable patient reported outcomes. GGAS without UL should be part of the surgical armamentarium in centers performing GAS.

In **chapter 3** a video article with the surgical technique of the scrotoplasty of gGAS without UL is presented together with surgical and the urological outcomes as described above.

In **chapter 4** the effectiveness of preoperative laser depilation of the neo-urethral donor site was assessed together with the correlation between urethral hair density and voiding. This was a retrospective study of 25 transgender men undergoing phalloplasty with UL. The cohort was divided into 2 groups: one with preoperative laser hair removal and the other without. Data on preoperative laser depilation treatments were obtained from the local laser center. Intraurethral images were captured via urethroscopy and used to rate hair density. Images of the contralateral forearm were used as a reference. Hair density was rated in terms of the number of hairs per view as: zero, low (1–9), moderate (10–19), or high (>20). Voiding was assessed using the IPSS questionnaire, a 24 hour FVC, and uroflowmetry. In the depilation group (n = 14) the hair reduction was significant, and hair density was downgraded on average by 1.0 points (95% confidence interval [CI] 0.5–1.5). The mean number of laser treatment sessions was 6 (range 2–10). In the no-depilation group (n = 11), hair density did not significantly differ between the urethra and the contralateral arm (mean difference 0.18, 95% CI 0.5–0.9). The majority of the patients reported mild voiding complaints (median IPSS score 7, range 2–28), and had a normal functional bladder capacity and a non-obstructed urinary flow with low postvoid volumes. The outcomes show that laser depilation reduces hair and intraurethral hair does not cause voiding complaints.

#### Part 2

In part two the experience and results of testicular and penile prostheses in the VU University Medical Center are presented.

**Chapter 5** describes the clinical outcomes and risk factors for postoperative complications of testicular prostheses implantation used for neo-scrotal augmentation in transgender men. A retrospective chart study was performed including all transgender men who underwent neo-scrotal augmentation with testicular implants between January 1992 and December 2018. Surgical characteristics, and outcomes (explantation due to infection, extrusion, discomfort, leakage) and postoperative complications were recorded. Risk factors on complications were identified, using uni- and multivariate analyses. Two hundred and six patients were identified, and the following prostheses were placed: Dow Corning (n = 22), Eurosilicone (n=12), Nagor (n=205), Polytech (n=10), Promedon (n=105), Prometel (n=22), Sebbin (n=44), and unknown (n=2). The mean clinical follow-up time was 11.5 ± 8.3 years. In 43 patients (20.8%), one or both prostheses were explanted due to infection, extrusion, discomfort, prosthesis leakage, or urethral problems. Currently, scrotoplasty according to Hoebeke and Monstrey is the most frequently performed technique. Data revealed that for this technique explantation occurred in 6 of 52 patients (11.5%). A history of smoking was a risk factor for postoperative infections and prosthesis explantation. In earlier years larger prostheses were immediately placed at scrotal reconstruction; however, a trend can be seen toward smaller and lighter testicular prostheses and delayed implantation. This data shows that over the years, scrotoplasty techniques and testicular prostheses preferences have changed and explantation rates have dropped. Strengths of this study include the number of patients, long clinical follow-up time, and completeness of data. Weaknesses of this study comprise amongst other things its retrospective nature and the high variability of prostheses and surgical techniques used.

In **chapter 6** a historical overview is given of surgical outcomes of penile prosthesis implantation in transgender men who have undergone

phalloplasty in the VU University Medical Center. Transgender men who underwent penile prosthesis implantation after phalloplasty between January 1989 and September 2018 were identified retrospectively. A chart study was performed recording: demographics, perioperative complications, and reoperations. A total of 32 transgender men were identified and the phalloplasty's performed were: 22 FRFF phalloplasty's, 5 ALT phalloplasty's, 4 ALT/FRFF phalloplasty's, and 1 fibular flap phalloplasty. The median age at prosthesis implantation was 36 (range 21-59) years, the mean BMI  $25.9 \pm 4.0$  kg/m<sup>2</sup>. At first implantation, 16 inflatable (AMS Dynaflex (n=13), AMS Ambicor (n=3)) and 16 malleable (Coloplast genesis (n=14), AMS Spectra (n=2)) prostheses were placed. Of these, 5 (16%) were removed/replaced because of infection, 2 (6%) because of leakage, 2 because of extrusion, 2 because of dislocation, 2 because of dysfunction and 1 (3%) because of pain. The postoperative course was completely uneventful in 10 (31.3%) patients. Of all implanted prostheses, including revision procedures (n=45), 21 (44%) were surgically replaced or removed. Outcomes of this overview show that prosthesis explantation, replacement or revision surgery occurs frequently after penile prosthesis implantation. Patients need to be well-informed preoperatively on these complication rates.

**Chapter 7** gives an overview of the preliminary experience with the ZSI 100 FTM malleable penile implant designed for phalloplastys. A retrospective chart study was conducted on surgical outcomes, postoperative complications and reason of implant failure. This was a multi-center study including 3 European centers for genital transgender surgery: Amsterdam, Stockholm, and Reykjavik, and 25 patients were retrospectively identified, with a mean age of  $36 \pm 9$  years at implantation. The mean time between prosthesis implantation and phalloplasty was  $3.6 \pm 2.5$  years. The phalloplasty's performed were: 10 free radial forearm flap (FRFF) phalloplasty, 6 anterolateral thigh flap (ALT) phalloplasty, 2 superficial circumflex iliac artery perforator (SCIP) phalloplasty, 1 groin flap phalloplasty, and 6 combination flap phalloplasty. The mean follow-up time was 6.3 months. Explantation of the prosthesis was performed in 8 patients (32%), (infection n=3, protrusion n=4, pubic pain n=1). In an additional 3 patients, the prosthesis was removed due to social limitations of the malleable implant. Of those with the prosthesis in place, 13 of 14 patients (93%) were able to engage in penetrative sexual intercourse. The outcomes of this study show that complication rate of the ZSI 100 FTM malleable penile implant is high at the start of the learning curve. Although designed specifically for the transgender community, not all transgender men will be eligible for this type of prosthesis. Individuals need to be well counseled on specific (dis)advantages of the prosthesis. This is the first study on the ZSI 100 FTM malleable penile implant prostheses in transgender men. It also provides information on the use of malleable prostheses; whereas current literature predominantly focusses on inflatable devices. Limitations comprise the small patient population, short follow-up time, and retrospective nature of the study.

### Part 3

In part three the process of the development of the decision aid for gGAS in transgender men is described. The next two chapters give the results of psychological and sexual functioning and well-being after gGAS in transgender men.

**Chapter 8** describes the process of the development of a decision aid (DA) for genital surgery in transgender men (DA-GST). The aid will be useful in assisting both transgender men and health care professionals (HCPs) in the shared decision making process regarding genital GAS. During this shared decision making process the most relevant domains for each specific individual need to be explored. A qualitative focus group study was performed and 5 focus groups were organized with both HCPs and transmen. These were led by an independent professional moderator. Data collected during the focus groups related to the treatment options were information deemed relevant by transgender men, and the arguments for or against each treatment option. The items were divided into the following themes: outcome, quality of life, environment, sexuality, and beliefs. At the end an online aid was developed to support transgender men with their decision-making process concerning all surgical options for removal of reproductive organs and genital GAS.

Strengths of this study are that the DA has been developed according to an iterative participatory design approach to fit the needs of both transgender men and HCPs. Issues that transgender men find important and relevant pertaining to genital GAS were translated into arguments that were incorporated in the DA-GST. The study is limited by the group that have participated. Not all arguments for or against specific surgical options may be covered by the DA-GST.

**Chapter 9** reports a longitudinal study of 21 transgender men at least 1 year after gGAS conducted to evaluate motivations for, and psychosexual outcomes after gGAS. Data were collected when the transgender men applied for surgery and at least 1 year after surgery. Data collection included semi-structured questionnaires on motivations for surgery, postoperative experiences, and standardized measures of psychological symptoms, body image, self-esteem, sexuality, and quality of life (pre- and postoperative). Information on surgical complications and corrections was retrieved from medical records. Most participants underwent phalloplasty with urethral lengthening using a FRFF. Although problematic voiding symptoms were prevalent, many participants were satisfied with their penile function. The strongest motivations to pursue penile surgery were confirmation of one's identity (100%), enabling sexual intercourse (78%), and voiding while standing (74%). No significant differences between postoperative and reference values have been observed for standardized measures. After surgery, transgender men were more sexually active (masturbation and with a partner) and used their genitals more frequently during sex compared with before surgery (31%:78%). These outcomes indicate that counseling and decision making for GAS in transgender men should be a highly personalized and interdisciplinary practice. Study strengths include its longitudinal design and the novelty of the studied outcomes. The main limitations include the sample size and the nature of the assessment.

**Chapter 10** reports a clinical follow-up study of experienced sexuality conducted in 38 transgender men at least one year after gGAS. Participants received a set of self-constructed questionnaires on sexual relationships and orientation, use of genitals during sexual contact, and the experienced influence of surgery on sexuality. Twenty-nine had received phalloplasty, nine metoidioplasty. The average follow-up time was 32 months. The majority reported to be sexually active. The use and enjoyment of both chest and genitals during sexual activity increased after surgery. Other areas of improvement included arousability, sexual interest, and pleasure. Free text comments provided an insight in the role of genital sensation and sexual self-esteem in postoperative sexuality. The outcomes of the data show that genital GAS positively impacts transmen's sexuality, although possible issues with genital sensation or penetration may exist and should be communicated preoperatively. Therefore, interdisciplinary collaboration is recommended on this subject.



## Samenvatting

De genitale chirurgische fase van het transitie proces bij transgender mannen kan de urologische anatomie en urologische functie veranderen. Dit pleit voor urologische betrokkenheid in deze fase van geslachtsaanpassing. De afdeling urologie is vanaf 2013 deel van het gender-team van het VU Medisch Centrum, en is verantwoordelijk voor het waarborgen van functionele resultaten zoals de mictie- en seksuele functie. Om deze functie te kunnen uitvoeren maken we deel uit van het chirurgische team tijdens de genitale geslachtsaanpassende operaties (gGAO) bij transgender mannen (reconstructie van het neoscrotum en de neourethra tijdens phalloplastiek, reconstructie van de neourethra tijdens metaidoioplastiek) en voeren wij zelfstandig procedures uit (plaatsing van testis en penis prothese, urethraplastiek, en uitvoering van secundaire correcties). Naast fysieke effecten kunnen de resultaten van deze operaties ook psychologische en sociaaleconomische gevolgen hebben. Daarom is het van belang dat de resultaten van deze procedures adequaat worden bijgehouden en geanalyseerd. Dit proefschrift bestaat uit drie delen die achtereenvolgens beschrijven: maatregelen genomen om postoperatieve urologische complicaties na gGAO te beperken, en of te voorkomen; ervaring en resultaten na implantatie van prothesen; de ontwikkeling van een beslisshulp voor genitale chirurgie voor transgender mannen; en de resultaten van psychologische en seksuele functioneren en welzijn na gGAO. Urologische betrokkenheid is bij al deze gebieden vereist.

## Introductie

Het eerste deel van de inleiding legt genderzorg uit, en de rest beschrijft de structuur van het proefschrift.

### Deel 1

Deel een beschrijft enkele aanpassingen uitgevoerd om urologische complicaties na gGAO bij transgender mannen te reduceren, of te voorkomen. **Hoofdstuk 2** beschrijft de functionele en chirurgische resultaten en patiënttevredenheid na een gGAO zonder plasbuisverlenging bij transgender mannen. Achteenzestig transgender mannen hebben deelgenomen aan het onderzoek voor deze studie. De International Prostate Symptom Score (IPSS), uroflowmetrie en 24 uren-mictielijst (ML) werden gebruikt om de plasfunctie (opslag en mictiefunctie) te beoordelen. Een zelf geconstrueerde semigestructureerde vragenlijst werd gebruikt voor patiënt-gerapporteerde uitkomst maten (patient reported outcome meusrus= PROM). De mediane follow-up tijd was 24 (6-129) maanden. Postoperatieve chirurgische en urologische complicaties traden op bij respectievelijk 9 (13%) en 8 (11%) patiënten. Opslag- en mictiefunctie bleven ongewijzigd. De mediane kwaliteit van leven (KvL) als gevolg van plasproblemen scoorde 'tevreden'. Achttien van de veertig patiënten 18/40 (45%) gaven aan seksueel "goed" te functioneren, en 21/40 (53%) patiënten beweerden "zeer tevreden" te zijn met hun mictie. Vijfentwintig van de veertig patiënten 25/40 (63%) waren tevreden met de penis, en 26/40 (65%) gaven bij de neo-scrotum "zeer bevredigend" aan, 32/40 (80%) rapporteerden een toegenomen zelfvertrouwen, 32/40 (68%) zou de operatie weer ondergaan, en 28/40 (70 %) zou het aanbevelen aan anderen. De uitkomsten van gGAO zonder UL, toont goede chirurgische en urologische resultaten aan. De meerderheid van deze geselecteerde groep rapporteert na een uitgebreide begeleiding gunstige resultaten. gGAO zonder UL moet deel uitmaken van het chirurgische armamentarium in centra die GAO uitvoeren.

**Hoofdstuk 3** toont een video over de chirurgische techniek van de scrotumplastiek van gGAO zonder plasbuisverlenging samen met chirurgische en urologische uitkomsten zoals hierboven beschreven.

In **hoofdstuk 4** wordt het effect van preoperatieve laserontharing van de neo-urethrale donorplaats geëvalueerd samen met de correlatie tussen urethrale haardichtheid en de mictie. Dit is een retrospectieve studie van 25 transgender mannen die een phalloplastiek met plasbuisverlenging hebben ondergaan. Het cohort was in 2 groepen verdeeld: één met preoperatieve laserontharing en de andere zonder. Intra-urethrale beelden werden vastgelegd via urethroscopie, en gebruikt om de haardichtheid te beoordelen. Afbeeldingen van de contralaterale onderarm werden gebruikt als referentie. De haardichtheid werd gedefinieerd als het aantal haren per gezichtsveld (haren/gezichtsveld) en werd gescoord als: geen (0 haren/gezichtsveld), laag (1-9 haren/gezichtsveld), matig (10-19 haren/gezichtsveld) of hoog (> 20 haren/gezichtsveld). De mictie werd beoordeeld met behulp van de IPSS vragenlijst, een 24 uren mictielijst, en uroflowmetrie. In de groep met ontharing (n=14) was haardichtheid significant laag, en de haardichtheid verminderde met gemiddeld met 1,0 punten (95% betrouwbaarheidsinterval [BI] 0,5-1,5). Het gemiddelde aantal laserbehandelingssessies was 6 (bereik 2-10). In de groep zonder ontharing (n=11) verschild de haardichtheid tussen de urethra en de contralaterale arm niet significant (gemiddeld verschil 0,18, 95% BI 0,5-0,9). Het merendeel van de patiënten rapporteerde lichte mictieklachten (mediaan IPSS score 7, bereik 2-28), had een normale functionele blaascapaciteit en een niet obstructieve mictie met lage residu. De uitkomsten laten zien dat laserontharing zorgt voor afname van haargroei en dat intra-urethraal haar geen mictieklachten veroorzaakt.

### Deel 2

Het tweede deel rapporteert ervaringen en resultaten van de testis en erectie prothese in het VU Medisch Centrum.

**Hoofdstuk 5** beschrijft klinische resultaten en risicofactoren voor postoperatieve complicaties na implantatie van testis prothese gebruikt voor neo-scrotum vergroting bij transgender mannen. Een retrospectieve statusonderzoek werd uitgevoerd waarbij alle transgender mannen die een neo-scrotum vergroting met testis prothese tussen januari 1992 en december 2018 hadden ondergaan werden geïncludeerd. Chirurgische kenmerken, en de resultaten (explantatie als gevolg van infectie, extrusie, ongemak, lekkage) en postoperatieve complicaties werden opgenomen. Risicofactoren op complicaties werden geïdentificeerd, met behulp van uni- en multivariate analyses. Tweehonderd zes patiënten werden geïdentificeerd, en de volgende prothesen werden geplaatst: Dow Corning (n=22), Eurosilicone (n=12), Nagor (n=205), Polytech (n=10), Promedon (n=105), Prometel (n=22), Sebbin (n=44) en onbekend (n=2). De gemiddelde klinische follow-up-tijd was 11,5 ± 8,3 jaar. Bij 43 patiënten (20,8%) werden één of beide prothesen geëxplanteerd vanwege infectie, extrusie, ongemak, protheselekkage of urethrale problemen. Momenteel is scrotumplastiek volgens Hoebeke en Monstrey de meest uitgevoerde techniek. Uit gegevens blijkt dat bij deze techniek explantatie optreedt bij 6 van de 52 patiënten (11,5%). Roken is een risicofactor voor postoperatieve infecties en prothese explantatie. Vroeger werden grotere prothesen direct geplaatst bij de reconstructie van het neo-scrotum; er is echter een trend

waarneembaar naar kleinere en lichtere testikelprothesen en implantatie op een later moment (minimaal 6 maanden na de gGBO). Uit deze gegevens blijkt dat door de jaren heen scrotumplastiek technieken en de voorkeur voor testis prothesen zijn veranderd, en dat explantatie cijfers zijn gedaald. Sterke punten van deze studie zijn onder meer het aantal patiënten, de lange klinische follow-up tijd, en volledigheid van de gegevens. Tekortkomingen van deze studie zijn onder andere zijn retrospectieve aard, en de hoge variabiliteit van prothesen en chirurgische technieken die worden gebruikt.

In **Hoofdstuk 6** wordt er een historisch overzicht gegeven van de chirurgische resultaten van de erectie prothese geïmplantéerd in transgender mannen die een phalloplastiek hebben ondergaan in het VU Medisch Centrum. Transgender mannen die deze procedure (implantatie erectie prothese) hebben ondergaan tussen januari 1989 en september 2018 werden achteraf geïdentificeerd. Er werd een statusonderzoek verricht waarin opgenomen werd: demografische gegevens, perioperatieve complicaties, en her-operaties. Een totaal van 32 transgender mannen is geïdentificeerd en de uitgevoerde phalloplastieken waren: 22 FRFF phalloplastieken, 5 ALT phalloplastieken, 4 ALT / FRFF phalloplastieken, en 1 fibula lap phalloplastiek. De mediane leeftijd bij prothese-implantatie was 36 (bereik 21-59) jaar, de gemiddelde BMI  $25,9 \pm 4,0 \text{ kg / m}^2$ . Bij de eerste implantatie werden 16 hydraulische (AMS Dynaflex (n = 13), AMS Ambicor (n = 3)) en 16 semirigide (Coloplast-genese (n = 14), AMS Spectra (n = 2)) prothesen geplaatst. Hiervan werden 5 (16%) verwijderd / vervangen vanwege infectie, 2 (6%) vanwege lekkage, 2 vanwege extrusie, 2 vanwege locatie, 2 vanwege disfunctie en 1 (3%) vanwege pijn. Het postoperatieve proces verliep ongecompliceerd bij 10 (31,3%) transgender mannen. Van alle geïmplantéerde prothesen, inclusief revisieprocedures (n=45), werden er 21 (44%) operatief vervangen of verwijderd. Uit dit overzicht komt naar voren dat prothese explantatie, vervanging of revisiechirurgie vaak voorkomt na implantatie van een penisprothese. Patiënten moeten preoperatief goed geïnformeerd zijn over deze complicatiepercentages.

**Hoofdstuk 7** geeft een overzicht van de ervaring met de ZSI 100 FTM semirigide erectie prothese welke speciaal is ontworpen voor de phalloplastiek. Een retrospectieve statusonderzoek werd uitgevoerd op chirurgische uitkomsten, postoperatieve complicaties, en de reden van falen van het implantaat. Dit was een multicenteronderzoek van 3 Europese centra voor genitale transgenderchirurgie: Amsterdam, Stockholm en Reykjavik, en 25 patiënten werden retrospectief geïdentificeerd, met een gemiddelde leeftijd van  $36 \pm 9$  jaar bij implantatie. De gemiddelde tijd tussen prothese-implantatie en phalloplastiek was  $3,6 \pm 2,5$  jaar. De uitgevoerde phalloplastieken waren: 10 vrije radiale onderarmflap (free radial forearmflap=FRFF) phalloplastieken, 6 anterolaterale bovenbeenlap (anterolateral thigh flap=ALT) phalloplastieken, 2 oppervlakkige circumflex iliacaal arterie perforator (superficial circumflex iliac perforator=SCIP) phalloplastieken, 1 lieslap phalloplastiek, en 6 combinatie flap phalloplastieken. De gemiddelde follow-up tijd was 6,3 maanden. Explantatie van de prothese werd uitgevoerd bij 8 patiënten (32%) (infectie n=3, erosie n=4, schaampijn n=1). Bij nog eens 3 patiënten werd de prothese verwijderd vanwege sociale beperkingen van het implantaat. Van degenen met de prothese in situ, konden 13 van de 14 patiënten (93%) geslachtsgemeenschap aangaan. De resultaten van dit onderzoek laten zien dat de complicatierisico van de ZSI 100FTM semirigide erectie prothese hoog is aan het begin van de leercurve. Hoewel speciaal ontworpen voor de phalloplastieken, komen niet alle transgendermannen in aanmerking voor dit type prothese. De transgender man moet goed worden geadviseerd over de specifieke nadelen van de prothese. Dit is de eerste studie over de ZSI 100FTM semirigide erectie prothesen in transgender mannen. Het geeft ook informatie over het gebruik van de prothesen; terwijl de huidige literatuur zich voornamelijk richt op hydraulische prothesen. Beperkingen omvatten een kleine patiënten populatie, de korte follow-up tijd en het retrospectieve karakter van de studie.

### Deel 3

In deel drie wordt het proces van ontwikkeling van een beslishulp voor gGAO bij transgender mannen beschreven. De volgende twee hoofdstukken geven de resultaten weer van psychologisch en seksueel functioneren en welzijn na gGAO bij transgender mannen.

**Hoofdstuk 8** beschrijft het proces van ontwikkeling van beslishulp (decision aid =DA) voor genitale chirurgie bij transgender mannen (decision aid for genital surgery in transgender men = DA-GST). De beslishulp zal nuttig zijn bij het bijstaan van zowel transgender mannen als de zorgverleners in de gezamenlijke besluitvorming over genitale GAO. Tijdens dit gezamenlijke besluitvormingsproces moeten de meest relevante aspecten voor elk specifiek individu onderzocht worden. Er werd een kwalitatieve focusgroep studie verricht, en er werden 5 focusgroepen georganiseerd met zowel zorgverleners als transgender mannen. Deze groepen werden geleid door een onafhankelijke professionele gespreksleider. De tijdens de focusgroepen verzamelde gegevens werden relevant geacht door de transgender mannen, en behelsden de argumenten voor of tegen elke behandeloptie. De gespreksonderwerpen waren onderverdeeld in de volgende thema's: uitkomst, kwaliteit van leven, omgeving, seksualiteit en overtuigingen. Aan het eind werd er een onlinehulp beslishulp ontwikkeld om transgender mannen te ondersteunen in het besluitvormingsproces met betrekking tot alle chirurgische opties van het verwijderen van voortplantingsorganen tot de gGAO. Sterke punten van deze studie zijn dat de beslishulp is ontwikkeld volgens een iteratief participatieve ontwerpbenadering van de behoeften van zowel transgender mannen als die van de zorgverleners. Problemen die transgender mannen belangrijk en relevant achten met betrekking tot gGAO zijn vertaald naar argumenten die zijn opgenomen in de DA-GST. Een beperking van de studie is de groep die heeft deelgenomen. Het kan zijn dat niet alle argumenten voor of tegen specifieke chirurgische opties gedekt zijn door de DA-GST.

**Hoofdstuk 9** doet verslag van een longitudinale studie onder 21 transgender mannen, die minstens 1 jaar na GAO is verricht om de motivatie voor, en psychoseksuele uitkomsten na gGAO te evalueren. Gegevens werden verzameld bij aanvraag van de transgender mannen voor een operatie, en tenminste een jaar na de ingreep. De verzamelde gegevens omvatte ingevulde semigestructureerde vragenlijsten over motivaties voor chirurgie, postoperatieve ervaringen en gestandaardiseerde metingen van psychologische symptomen, lichaamsbeeld, zelfrespect, seksualiteit, en kwaliteit van het leven (pre- en postoperatief). Informatie over chirurgische complicaties en correcties werd gehaald uit medische dossiers. De meeste deelnemers ondergingen phalloplastiek met urethrale verlenging met behulp van een FRFF. Hoewel er veel mictie klachten voorkwamen, waren veel deelnemers tevreden met hun mictiefunctie. De voornaamste redenen om GAO te ondergaan, waren bevestiging van identiteit (100%), mogelijkheid tot seksuele gemeenschap (78%), en staand kunnen plassen (74%). Er zijn voor uitkomsten van de gestandaardiseerde vragenlijsten geen significante verschillen waargenomen tussen postoperatieve en referentiewaarden. Na de operatie waren transgender mannen seksueel actiever (masturbatie en met een partner) en gebruikten hun geslachtsdelen vaker tijdens seks, vergeleken bij vóór de operatie (31 %: 78%). Deze uitkomsten geven aan dat begeleiding en besluitvorming voor GAO bij transgender mannen

zeer persoonlijke is, en onderschrijven het belang van multidisciplinaire samenwerking. De sterke punten van het onderzoek zijn onder meer de longitudinale opzet en de noviteit van de resultaten. De belangrijkste beperkingen zijn de populatie grootte en de aard van de beoordeling. **Hoofdstuk 10** verslaat een klinische follow-up studie over seksualiteit verricht onder 38 transgender mannen ten minste één jaar na gGAO. De deelnemers ontvingen een reeks zelfgemaakte vragenlijsten over seksuele relaties en oriëntatie, het gebruik van geslachtsdelen tijdens seksueel contact, en de ervaren invloed van chirurgie op seksualiteit. Negenentwintig transgender mannen hadden phalloplastiek ondergaan, en negen metaidoioplastiek. De gemiddelde follow-up tijd was 32 maanden. De meerderheid meldde seksueel actief te zijn. Het gebruik en genot van zowel de borst als de geslachtsdelen tijdens seksuele activiteit nam na de operatie toe. Andere verbeterpunten waren opwinding, seksuele interesse en plezier. Vrije tekst commentaar verschaftte inzicht in de rol van genitale sensatie en seksuele zelfvertrouwen bij postoperatieve seksualiteit. De resultaten van de gegevens laten zien dat gGAO een positieve invloed heeft op de seksualiteit van transgender mannen, hoewel er mogelijk problemen zijn met genitale sensatie of penetratie en deze preoperatief moeten worden gecommuniceerd. Daarom wordt multidisciplinaire samenwerking over dit onderwerp aanbevolen.

## Curriculum vitae

Garry Lester Sergio Pigot werd op 1 maart 1972 geboren te Groningen Nederland en groeide op als de middelste zoon van Cor Pigot en Carmen Pigot Nahar. De familie remigreerde naar Paramaribo Suriname in 1973. In 1992 rondde hij het Voorbereidend Wetenschappelijk Onderwijs af op het

Mr. Dr. J.C. de Miranda Lyceum in Paramaribo. Van 1992 tot 1994 studeerde hij geneeskunde aan het Rijks Universitair Centrum Antwerpen. In 1994 begon hij aan de geneeskunde studie aan de Universiteit van Amsterdam en hij behaalde 1995 zijn propedeuse. Zijn artsen examen haalde hij in 2001. Van 2001 tot en met 2004 was hij werkzaam als ANIOS op de afdeling heelkunde eerste in het Amstelland ziekenhuis en later in het Boven IJ Ziekenhuis. In 2004 begon hij als ANIOS urologie in het VUMC. Hij startte in 2006 met de vooropleiding heelkunde in het VUMC (prof. dr. J.A. Rauwerda) en vervolgde de opleiding urologie in het VUMC (prof. dr. E.J.H. Meuleman) en het Sint Lucas Andreas Ziekenhuis (drs. E. Heldeweg). In 2012 was hij fellow urologische oncologie in het Anti van Leeuwenhoek ziekenhuis (prof. dr. S.Horenblas). Sinds 2013 is hij werkzaam op de afdeling urologie van het VUMC. In 2013 als fellow andrologische en reconstructieve urologie (prof. dr. E.J.H. Meuleman) en genitale gender chirurgie (prof. dr. B.-M. Bouman). Sinds 2015 is hij stafid van de afdeling urologie met als werkgebied: genitale reconstructie bij cis mannen, prothesiologie bij cis mannen, andrologie en genitale chirurgie bij trans genders, prothesiologie bij trans gender mannen.

Sinds 2013 maakt hij deel uit van het gender team in het VUMC.

Hij is sinds 2015 lid van de werk groep andrologie van de Nederland Vereniging voor Urologie (NVU) en is lid van de Dutch Urologist involved in Urethral Recosntruction (DUUR) werkgroep.

Vanaf 2016 is hij Fellow of the European Society of Sexual Medicine. Hij is sinds 2016 werkplek manager van de poli urologie van het VUMC

Garry Lester Sergio Pigot was born on March 1, 1972 in Groningen, the Netherlands and grew up as the middle son of Cor Pigot and Carmen Pigot Nahar. The family went back to Paramaribo Suriname in 1973. In 1992 he completed high school at the Mr.Dr.J.C. the Miranda Lyceum in Paramaribo. From 1992 to 1994 he studied medicine at the Rijks Universitair Centrum Antwerpen (Antwerp). In 1994 he started studying medicine at the University of Amsterdam and obtained his propaedeutic in 1995. He passed his medical exam in 2001. From 2001 to 2004 he worked as non-resident in the surgery department in the Amstelland hospital and later in the Boven IJ Hospital. In 2004 he started as non-resident urology at the VUMC. He started in 2006 with the training in surgery at the VUMC (prof. dr. J.A. Rauwerda) and continued his training in urology at the VUMC (Prof. Dr. E.J.H. Meuleman) and the Sint Lucas Andreas Hospital (drs. E. Heldeweg). In 2012 he was a fellow urological oncology at the

Anti van Leeuwenhoek Hospital (prof. dr. S. Horenblas).

He has been working in the urology department of the VUMC since 2013. In 2013 as a fellow in Andrology and Reconstructive Urology (prof. dr. E.J.H. Meuleman) and Genital Gender Surgery (prof. dr. M.-B. Bouman). Since 2015 he has been a staff member of the department of urology with the following activities: genital reconstruction for cis men, prosthetics for cis men, andrology and genetic surgery for transgender genders, prosthetics for transgender men.

Since 2013 he has been part of the gender team at the VUMC.

He has been a member of the andrology working group of the Netherlands Association for Urology (NVU) since 2015 and is a member of the Dutch Urologist involved in Urethral Reconstruction (DUUR) working group.

As of 2016 he is a Fellow of the European Society of Sexual Medicine. He has been the workplace manager of the outpatient clinic of the department of urology since 2016 of the VUMC.

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